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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

NORTH SOUND CAPITAL LLC; NORTH SOUND LEGACY INTERNATIONAL; NORTH SOUND LEGACY INSTITUTIONAL; UNITED FOOD COMMERCIAL WORKERS LOCAL 1500 PENSION FUND; COLONIAL FIRST STATE INVESTMENTS LTD.; CFSIL – CFS WHOLESALE INDEXED GLOBAL SHARE FUND; COMMONWEALTH BANK OFFICERS SUPERANNUATION CORPORATION AS TRUSTEE FUND OFFICERS SUPERANNUATION FUND – WGSS04; CFSIL – COMMONWEALTH GLOBAL SHARES FUND 4; COMMONWEALTH BANK OFFICERS SUPERANNUATION CORPORATION AS TRUSTEE FUND OFFICERS SUPERANNUATION FUND – WGSS02; COMMONWEALTH BANK OFFICERS SUPERANNUATION CORPORATION AS TRUSTEE FUND OFFICERS SUPERANNUATION FUND – WTRA02; CFSIL – COMMONWEALTH SPECIALIST FUND 13; CFSIL – CFS WHOLESALE GEARED GLOBAL SHARED FUND; CFSIL ATF CMLA INTERNATIONAL SHARE FUND; CFSIL – COMMONWEALTH GLOBAL SHARES FUND 6; CFSIL – COMMONWEALTH GLOBAL SHARES FUND 2; CFSIL – CFS WHOLESALE ACADIAN GLOBAL EQUITY FUND; CFSIL – CFS WHOLESALE GLOBAL HEALTH & BIOTECHNOLOGY FUND; CFSIL – CFS WHOLESALE GLOBAL SHARE FUND, Plaintiffs, v. MERCK & CO., INC. F/K/A SCHERING-PLOUGH CORPORATION; MERCK/SCHERING-PLOUGH PHARMACEUTICALS; MSP DISTRIBUTION SERVICES (C) LLC; MSP SINGAPORE COMPANY LLC; FRED HASSAN; CARRIE S. COX, Defendants.	CIVIL ACTION NO: _____ COMPLAINT JURY TRIAL DEMANDED

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North Sound Capital LLC, North Sound Legacy International, North Sound Legacy Institutional (collectively, "North Sound"), United Food Commercial Workers Local 1500 Pension Fund ("Local 1500"), Colonial First State Investments Ltd., CFSIL - CFS Wholesale Indexed Global Share Fund, Commonwealth Bank Officers Superannuation Corporation as Trustee Fund Officers Superannuation Fund - WGSS04, CFSIL - Commonwealth Global Shares Fund 4, Commonwealth Bank Officers Superannuation Corporation as Trustee Fund Officers Superannuation Fund - WGSS02, Commonwealth Bank Officers Superannuation Corporation as Trustee Fund Officers Superannuation Fund - WTRA02, CFSIL - Commonwealth Specialist Fund 13, CFSIL - CFS Wholesale Geared Global Share Fund, CFSIL ATF CMLA International Share Fund, CFSIL - Commonwealth Global Shares Fund 6, CFSIL - Commonwealth Global Shares Fund 2, CFSIL - CFS Wholesale Acadian Global Equity Fund, CFSIL - CFS Wholesale Global Health & Biotechnology Fund, and CFSIL - CFS Wholesale Global Share Fund (collectively "Colonial First"),[1] by their undersigned counsel, bring this action for violations of the federal securities laws and New Jersey common law against Defendants Merck & Co., Inc. f/k/a Schering-Plough Corporation ("Schering," "Schering-Plough," or the "Company"), two former members of the Company's senior management, Fred Hassan and Carrie S. Cox, and M/SP (as defined below) (Schering, M/SP, Fred Hassan, and Carrie S. Cox are referred to collectively herein as "Defendants" and are defined further below). The allegations in this Complaint are based on Plaintiffs' knowledge as to themselves, and on information and belief, including the investigation of counsel and pleadings filed in related litigation, as to all other matters. The investigation of counsel is predicated upon, among other things, review and analysis

[1] North Sound, Local 1500, and Colonial First are collectively referred to herein as "Plaintiffs."

of: (i) Schering's and Merck & Co. Inc. ("Merck")'s public filings with the U.S. Securities and Exchange Commission ("SEC"); (ii) medical journals and other publicly-available materials concerning a clinical trial entitled "Ezetimibe and Simvastatin in Hypercholesterolemia Enhances Atherosclerosis Regression," more commonly known as "ENHANCE"; (iii) publicly-available information concerning Schering, M/SP, and Merck, including documents uncovered by investigations of Schering and Merck by the United States Senate Committee on Finance (the "Senate Finance Committee") and the United States House of Representatives Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations (the "House Oversight Subcommittee") into the delayed release of the ENHANCE trial's results; (iv) documents filed in other actions, including filings in *In re Merck & Co., Inc. Vytorin/Zetia Securities Litigation*, No. 08-cv-2177 (DMC) (JAD) (D.N.J.) (the "Merck Class Action") and *In re Schering-Plough Corporation/ENHANCE Securities Litigation*, No. 08-cv-397 (DMC) (JAD) (D.N.J.) (the "Schering-Plough Class Action"); (v) analyses of Schering executives' trading in Schering securities; (vi) press releases, conference call transcripts, presentation materials, and media reports about the Defendants; (vii) publicly-available data relating to the prices and trading volumes of Schering's securities; and (viii) reports issued by securities analysts who followed Schering. Plaintiffs believe that substantial, additional evidentiary support for the allegations set forth herein will be obtained after a reasonably opportunity for discovery.

NATURE OF THE ACTION

1. This lawsuit asserts claims for common law fraud and for violations of Sections 10(b), 20(a), and 20A of the Securities Exchange Act of 1934 (the "Exchange Act") against Defendants for concealing material information and making false and misleading statements which artificially inflated the value of Schering securities during the period of January 3, 2007 through

March 28, 2008 (the "Relevant Period"). Later disclosures caused the Schering securities' prices to decline, causing injury to Plaintiffs.

2. Specifically, this action arises from Defendants' material misrepresentations and omissions concerning the commercial viability of two prescription drug products that Schering co-markets with Merck through the M/SP joint venture – the anti-cholesterol agents Zetia and Vytorin.

3. Cholesterol-lowering drugs, and particularly the class of drugs known as "statins," are the most prescribed products in the history of the pharmaceutical industry. Statins work by inhibiting the synthesis of low density lipoprotein ("LDL") or "bad" cholesterol in the liver. In other words, statins disrupt the biological processes that cause the body to produce LDL cholesterol. However, lowering cholesterol levels in the bloodstream is not the ultimate goal of initiating drug therapy; this measurement is only a surrogate. The true test of whether a drug is effective is whether it beneficially affects how a patient feels, functions, or survives. Statins have long been recognized as the "gold standard" first-line treatment for patients with high LDL cholesterol because they have been shown in clinical trials to provide the potential for reducing the risk of future cardiovascular disease or events such as heart attacks and strokes and for increasing overall survival rates in certain patient populations.

4. Ezetimibe, the active pharmaceutical ingredient in Zetia, is not a statin; it is in a class of drugs that inhibits the absorption of intestinal cholesterol (*e.g.*, cholesterol in food). Vytorin is a "fixed-dose combination" pill comprised of two active pharmaceutical ingredients: Zetia (ezetimibe) and simvastatin, a drug in the statin class that Merck markets separately under the brand name Zocor. And unlike with statins, prior to and throughout the Relevant Period, there

were no clinical trials demonstrating that the use of ezetimibe to lower LDL cholesterol levels prevents heart disease or cardiovascular-related deaths. ENHANCE was one of a series of clinical trials designed to help fill that gap.

5. Although ENHANCE was not structured to compare "clinical endpoints" such as heart attacks or cardiovascular-related deaths, it did seek to determine whether the ezetimibe/simvastatin combination in Vytorin had more marked beneficial effects than simvastatin alone on the progression of the disease underlying most cardiovascular events – atherosclerosis, the disease process by which plaque builds up in the walls of the arteries.

6. The results of ENHANCE were of great public interest and highly anticipated since, as the New York Times observed on December 12, 2007: "Independent scientists have viewed ENHANCE as crucial because it is the first trial that would answer whether Zetia's ability to lower cholesterol has real biological benefits for patients."

7. Prior to and throughout the Relevant Period, ENHANCE was complete, but the results were an unqualified disaster. While the patients in the ENHANCE trial who took Vytorin did, on average, record significantly lower levels of LDL cholesterol than the patients who took Zocor, no significant difference emerged between the two groups on the study's ***primary endpoint*** or ***outcome measure*** – the mean change in the thickness of the walls of patients' carotid arteries. In other words, adding ezetimibe to cheaper simvastatin added no benefit in slowing the progression of atherosclerosis. As cardiologist Dr. Harlan Krumholz of Yale University stated after the results were finally released, ENHANCE raised the possibility that ezetimibe is only an ***"expensive placebo."***

8. Defendants failed to inform the market of those disastrous results for over a year. Instead, they made numerous public disclosures prior to and throughout the Relevant Period emphasizing the multi-billion dollar sales of Zetia and Vytorin, emphasizing that Vytorin's ability to lower cholesterol was "clearly better" than competing statin products such as Pfizer's Lipitor and AstraZeneca's Crestor, and declaring that "the science is favoring Vytorin and Zetia."

9. Schering's numerous disclosures during the Relevant Period were materially false and misleading when made because they failed to disclose the adverse results of ENHANCE, which contradicted the Company's repeated assertions that the "science" was favoring Zetia and Vytorin, and which were plainly material to investors such as Plaintiffs, as Schering repeatedly recognized in its SEC filings and other public statements.

10. Schering withheld material information concerning the ENHANCE results from the market until early 2008 based on purported problems with the data, but during the Relevant Period continued to issue highly positive statements regarding Zetia and Vytorin even though:

- Schering knew as early as the ***summer of 2006, "that they were not going to get any good news"*** from ENHANCE. According to the Amended Complaint in the Schering-Plough Class Action, Confidential Witness 1 ("CW 1"), a former Senior Medical Director in Schering's Cardiovascular Therapeutics group from November 2004 until September 2006, interacted with Schering's "Brand Team" on a daily basis regarding Zetia and Vytorin. As set forth below, CW 1 also confirmed that Schering performed a quality control assessment of ENHANCE data in late 2005 to early 2006. A Wall Street Journal article published in 2008 confirmed this information. CW 1 also confirmed that updates regarding ENHANCE were shared in quarterly Brand Review Meetings CW 1 attended. Defendant Carrie Cox, a Schering Executive Vice President and President of Global Pharmaceuticals, led these meetings;

- ***In January 2007,*** an independent consultant retained by Schering to assess ENHANCE data quality told Schering that the quality of the data collected to measure arterial wall thickness was ***"fine; i.e., no better, no worse than what [had] been reported in [other similar studies],"*** and was therefore suitable for publication;

- ***As early as March 2007*** and continuing throughout the summer and fall of 2007, posts appeared on the pharmaceuticals website CaféPharma.com strongly suggesting that Schering insiders knew the ENHANCE results were a "bust." While the accuracy of such posts was of course known by individual Defendants at the time given their familiarity with the results, the public could not appreciate their weight until 2008, when specific study findings mentioned in the posts were substantiated by the Company;

- ***In July 2007***, ENHANCE's Principal Investigator expressed shock to the Schering personnel responsible for ENHANCE when the Company scrapped plans to release the results at a November 2007 medical conference: ***"This starts smelling like extending the publication for no other [than] political reasons and I cannot live with that . . . you will be seen as a company that tries to hide something and I will be perceived as being in bed with you !"***;

- In November 2007 – nineteen months after the study had been completed – Schering attempted to alter ENHANCE's primary endpoint, a maneuver that would have skewed the results to focus on the only site of arterial wall measurement that slightly favored Vytorin; and

- In December 2007, Schering created inaccurate after-the-fact "minutes" of a November 2007 meeting of outside consultants in a failed attempt to make it appear as though the consultants were the driving force behind Schering's attempt (later abandoned) to change ENHANCE's primary endpoint.

11. The market reacted negatively to Schering and M/SP's release of partial, top-line ENHANCE results in January 2008 (which preliminary results were only made public in response to pressure from Congress), but even that disclosure did not prepare the market for the full weight of the ENHANCE failure. In March 2008 – ***twenty three months*** after completion of the trial – the market was shocked when ENHANCE's Principal Investigator was finally permitted to reveal that Vytorin provided ***"no result – zilch. . . . In no subgroup, in no segment, was there any added benefit"*** when comparing the atherosclerotic process in Vytorin patients versus simvastatin patients. In fact, although Vytorin lowered LDL cholesterol more than simvastatin in the trial, artery wall thickness ***increased*** slightly more for patients administered Vytorin than for those patients administered simvastatin. Therefore, in ENHANCE, Vytorin's

lowering of LDL cholesterol was not, as Schering had repeatedly claimed, "clearly better" for patients than competing drugs.

12. The results were particularly damaging to Schering not only because Vytorin was no better than the statin in ENHANCE, it was no better than a generic statin. Merck had earlier lost its patent protection for Zocor and lower-priced generic simvastatin products began entering the market in June 2006 – before the start of the Relevant Period and before Schering was initially supposed to publish the ENHANCE results. ENHANCE thus immediately called into serious question the practice of prescribing Vytorin, a premium-priced branded product, when equally-effective and much less expensive generic alternatives were available. The delay in the release of the ENHANCE results allowed Schering to reap billions of dollars in sales of Zetia and Vytorin that would not have been made had ENHANCE been made public earlier, allowed Schering to project billions of dollars in future revenue tied to these drugs, and artificially inflated the market price of Schering's publicly-traded securities. Plaintiffs hereby bring claims against each of the Defendants named in this action for the losses caused by their respective misconduct.

CLAIMS ASSERTED IN THIS COMPLAINT

13. This Complaint sets forth claims under, *inter alia*, Sections 10(b), 20(a), and 20A of the Exchange Act, 15 U.S.C. §§ 78j(b), 78t(a), and the rules and regulations promulgated thereunder, including SEC Rule 10b-5, 17 C.F.R. § 240.10b-5 ("Rule 10b-5"), against Schering, M/SP, and the two former Schering officers named herein, who were knowing or reckless participants in defrauding investors in connection with their material misrepresentations and omissions concerning the ENHANCE results.

14. This Complaint also sets forth common law fraud claims under New Jersey law against Schering, M/SP, and the two former Schering officers named herein, who were knowing or reckless participants in defrauding investors in connection with their material misrepresentations and omissions concerning the ENHANCE results.

JURISDICTION AND VENUE

15. This Court has jurisdiction over the subject matter of this action pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa, and 28 U.S.C. §§ 1331, 1337 and 1367.

16. Venue is proper in this District pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa. Many of the acts and transactions that constitute the violations of law complained of herein, including the dissemination to the public of untrue statements of material facts, occurred in this District.

17. In connection with the acts alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the U.S. mails, interstate telephone communications, and the facilities of national securities exchanges.

PARTIES

I. Plaintiffs

A. North Sound

18. North Sound Capital LLC is a financial services firm that provides services to pooled investment vehicles. North Sound Legacy International and North Sound Legacy Institutional are two of the funds managed by North Sound Capital LLC. North Sound Capital LLC, North Sound Legacy Institutional, and North Sound Legacy International are headquartered at 3 Greenwich

Office Park, Suite 102, Greenwich, Connecticut 06831. Both North Sound Capital LLC and North Sound Legacy Institutional are incorporated in the State of Delaware. North Sound Legacy International is incorporated in the British Virgin Islands. During the Relevant Period, North Sound Capital LLC served as investment advisor for the North Sound Legacy International and the North Sound Legacy Institutional funds, and in that capacity, North Sound Capital LLC purchased millions of shares of Schering common stock[2] at prices that were artificially inflated as a result of Schering's misconduct. Because Schering's public disclosures omitted material information and were materially false and misleading, North Sound suffered substantial losses on its investments.

B. Local 1500

19. Local 1500 is a public pension fund chartered in 1937 for the benefit of food and commercial workers. Local 1500 primarily represents workers in the supermarket industry in the New York area and represents over 22,000 members. Local 1500 is located at 425 Merrick Avenue, Westbury, New York 11590. During the Relevant Period, Local 1500 purchased tens of thousands of shares of Schering common stock[3] at prices that were artificially inflated as a result of Schering's misconduct. Because Schering's public disclosures omitted material information and were materially false and misleading, Local 1500 suffered substantial losses on its investments.

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[2] North Sound's trade data during the Relevant Period is attached hereto as Exhibit A.

[3] Local 1500's trade data during the Relevant Period is attached hereto as Exhibit B.

C. Colonial First

20. Colonial First State Investments Ltd., a subsidiary of the Commonwealth Bank of Australia, is an investment management firm that provides investment, superannuation, and retirement products to individual, corporate, and superannuation fund investors. Colonial First is located at 11 Harbour Street, Sydney NSW 2000. During the Relevant Period, various funds managed by Colonial First State Investments Ltd., including, *inter alia*: CFSIL - CFS Wholesale Indexed Global Share Fund, Commonwealth Bank Officers Superannuation Corporation as Trustee Fund Officers Superannuation Fund - WGSS04, CFSIL - Commonwealth Global Shares Fund 4, Commonwealth Bank Officers Superannuation Corporation as Trustee Fund Officers Superannuation Fund - WGSS02, Commonwealth Bank Officers Superannuation Corporation as Trustee Fund Officers Superannuation Fund - WTRA02, CFSIL - Commonwealth Specialist Fund 13, CFSIL - CFS Wholesale Geared Global Share Fund, CFSIL ATF CMLA International Share Fund, CFSIL - Commonwealth Global Shares Fund 6, CFSIL - Commonwealth Global Shares Fund 2, CFSIL - CFS Wholesale Acadian Global Equity Fund, CFSIL - CFS Wholesale Global Health & Biotechnology Fund, and CFSIL - CFS Wholesale Global Share Fund, purchased over a million shares of Schering common stock[4] at prices that were artificially inflated as a result of Schering's misconduct. Because Schering's public disclosures omitted material information and were materially false and misleading, Colonial First suffered substantial losses on its investments.

[4] Colonial First's trade data during the Relevant Period is attached hereto as Exhibit C.

II. Defendants

A. Merck & Co., Inc. f/k/a Schering-Plough Corporation

21. Defendant Merck & Co., Inc. ("Merck") is a New Jersey corporation with its principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889-0100. Merck is a global pharmaceutical company that develops, manufactures, and markets a broad range of health care products. Merck and Schering-Plough Corporation, formerly a New Jersey corporation, completed their merger transaction on November 3, 2009, which was implemented by means of a two-step merger process. In the first merger, a wholly-owned subsidiary of Schering-Plough Corporation merged into Schering-Plough Corporation. The surviving entity is now known as New Merck. In the second merger, a second wholly-owned subsidiary of Schering-Plough Corporation merged into Merck. Merck continued as the surviving company in the second merger, but as a wholly-owned subsidiary of New Merck. Schering-Plough's stock ceased trading, and the combined company is now known as Merck & Co., Inc., with shares trading under the ticker symbol MRK on the New York Stock Exchange. Under the terms of the transaction, Schering-Plough's shareholders received approximately 0.58 shares of the newly-combined company's stock and $10.50 in cash for each Schering-Plough share. Each Merck share automatically converted into one share of the new company's stock. References to "Schering," "Schering-Plough," or the "Company" in this Complaint refer to Schering Plough Corporation during the Relevant Period, which was prior to the merger. During the Relevant Period, according to its public filings, the Company developed, manufactured, and marketed medical therapies and treatments worldwide. Throughout the Relevant Period, the two most commercially successful prescription drug products contributing to Schering's revenues and

profits were Vytorin and Zetia. Prior to and throughout the Relevant Period, Schering issued false and misleading statements to investors, including Plaintiffs.

B. Merck/Schering-Plough Pharmaceuticals, MSP Distribution Services (C) LLC, and MSP Singapore Company LLC

22. Defendants Merck/Schering-Plough Pharmaceuticals, MSP Distribution Services (C) LLC, and MSP Singapore Company LLC (collectively "M/SP") are entities that did business as "Merck/Schering-Plough Pharmaceuticals" during the Relevant Period. M/SP is a joint venture between Schering and Merck with its headquarters located at 351 N. Sumneytown Pike, P.O. Box 1000, North Wales, Pennsylvania 19454. MSP Distribution Services (C) LLC is the corporate entity that was doing business under the name Merck/Schering-Plough Pharmaceuticals. MSP Singapore Company LLC is the corporate parent entity of the joint venture. Schering and Merck formed M/SP in May 2000 to jointly develop and market in the United States new prescription medicines in cholesterol management, including Vytorin. During the Relevant Period, M/SP issued false and misleading statements to investors, including Plaintiffs.

C. The Officer Defendants

23. Defendant Fred Hassan ("Hassan") served as the Company's Chief Executive Officer ("CEO"), President, and Chairman from April 2003 until Schering's merger with Merck in November 2009. During the Relevant Period, Hassan disseminated false and misleading information to investors during the Company's earnings calls, and signed and certified the Company's false and misleading SEC filings.

24. Defendant Carrie S. Cox ("Cox") served as a Schering Executive Vice President and President of the Company's Global Pharmaceuticals Business from May 2003 until Schering's

merger with Merck in November 2009. During the Relevant Period, Defendant Cox disseminated false and misleading information to investors, including Plaintiffs, during the Company's earnings calls, and sold over $28 million of her Schering common stock while in possession of material, adverse non-public information about the Company.

SUBSTANTIVE ALLEGATIONS

25. As discussed below, each of the Defendants is liable as a participant in a fraudulent scheme and course of business that operated as a fraud or deceit on Plaintiffs – purchasers of Schering securities – by disseminating materially false and misleading statements and/or concealing material adverse facts regarding the failure of the ENHANCE trial. The scheme: (i) deceived Plaintiffs and the investing public regarding Schering's business, operations, management, and the intrinsic value of Schering securities; (ii) enabled Defendants to artificially inflate the price of Schering securities; (iii) enabled Schering insider Cox to sell over $28 million of her privately-held Schering shares and allowed the Company itself to register and sell over $4.08 billion in newly-issued securities during the Relevant Period while in possession of material, adverse, non-public information about the Company; and (iv) caused Plaintiffs to purchase Schering securities at artificially-inflated prices.

I. The Success of Schering's "Cholesterol Franchise" Was Critically Important to the Company's Corporate Turn-Around and Overall Financial Success

A. Historically, Schering Faced Significant Hurdles to Profitability

26. In early 2003, Schering faced serious legal, regulatory, and business problems. The U.S. Food and Drug Administration ("FDA") had recently fined Schering a record $500 million for poor manufacturing practices; the FDA was forcing the Company to operate its factories under a consent decree that was, in the Company's words, "unprecedented in the scope of remediation

and revalidation requirements"; the Company was under an SEC investigation, later settled, over meetings its former CEO Richard Jay Kogen held with selected investors; and the federal government was investigating Schering for allegedly defrauding Medicaid.[5] In addition, Schering's blockbuster allergy pill Claritin had recently lost patent protection and competition from generic versions of the drug was quickly eroding the $3 billion in annual sales that Claritin had generated. The Company was facing what it described as "severe cash flow pressures" and "the urgent need to upgrade [its] infrastructure in many areas."

27. On April 20, 2003, the Schering Board of Directors recruited Defendant Hassan as CEO to replace former CEO Kogen and, on April 22, 2003, elected Hassan as a Director and Chairman of the Board. In an April 20, 2003 press release, Schering expressed optimism that Hassan had the experience and skills to turn around the Company's finances and reputation, stating that the day marked "the beginning of a new era" for the Company.

28. Before joining Schering, Hassan had a reputation as a "turn-around specialist" in the pharmaceuticals industry based on his years as CEO of Pharmacia Corp. While Hassan served as Pharmacia's CEO, that company's profitability improved significantly, Pharmacia acquired Monsanto to gain control of the blockbuster arthritis drug Celebrex, and Pharmacia was sold to Pfizer for $60 billion in 2002. Upon joining Schering, Hassan faced pressure to improve Schering's ailing reputation and profitability in the same way he had done at Pharmacia.

[5] The Company pleaded guilty in 2004 to kickback claims related to Medicaid fraud, agreeing to pay $346 million in fines and damages.

B. Schering's Cholesterol Joint Venture Was Schering's "Savior"

29. When Hassan joined Schering, The Wall Street Journal identified his and the Company's one key prospect of hope: "Mr. Hassan's success may depend on his ability to hawk Zetia." Another article, written in October 2003, likewise recognized the potential significance of Schering's "cholesterol franchise" (*i.e.*, Zetia and Vytorin) in the wake of the "evaporation of Claritin sales":

> The company's greatest hope for reviving earnings is new cholesterol drug Zetia and a pill containing Zetia and Merck and Co.'s Zocor. The partners later this year plan to ask U.S. regulators to approve the combination cholesterol drug.
>
> ***"Zetia and the Zetia/Zocor combination is the big savior. That could drive a lot of earnings growth for them,"*** said [A.G. Edwards analyst Albert] Rauch, who projects $1 billion in Zetia sales next year.

(Emphasis added).

30. Despite all the ills Hassan inherited when he took over Schering, one thing prior management appeared to have done right was to strike a deal with Merck to form the M/SP joint venture. M/SP is the vehicle through which Schering and Merck co-market Zetia and Vytorin. With the development of Zetia, Schering was a newcomer to the cholesterol market. Partnering with Merck allowed Schering to benefit from Merck's significant experience in the cholesterol marketplace and gain access to Merck's significant marketing resources. Merck saw the development of a single pill that could combine Zocor with Zetia, a novel agent for lowering cholesterol, as a means to extend Zocor's life-cycle despite the impending loss of patent protection for Zocor.

31. In October 2002, the FDA approved Zetia. It was in a new class of cholesterol-lowering drugs, known as cholesterol absorption inhibitors. Unlike statins, which reduce cholesterol production in the liver, Zetia reduces cholesterol by inhibiting the body's absorption of the cholesterol found in food. In July 2004, the FDA approved Vytorin. Vytorin combines in a single pill Merck's Zocor, a statin, with Zetia. Vytorin was marketed to compete head-to-head with statins such as AstraZeneca's Crestor and Pfizer's Lipitor, among others. By combining both Zocor and Zetia in one pill, Vytorin lowers LDL cholesterol more than some doses of statins alone because Vytorin was designed to reduce both the body's production and absorption of cholesterol. Schering shares in 50% of the sales of Zetia and Vytorin through M/SP.

32. Early predictions of the importance of Zetia and Vytorin to Schering's bottom line turned out to be prescient. An August 2, 2006 article in The Wall Street Journal profiling Hassan stated that Schering had "struggled to come up with new drugs to replace big sellers like Claritin that have come off patent." While Schering had certain drugs in early development, such compounds often fail in later stages of human testing, and Schering's pipeline lacked compounds in late-stage testing. As Hassan acknowledged, "It's fair to say we have a late-stage pipeline gap."

33. Before and during the Relevant Period, Zetia and Vytorin became critical to Schering's financial success. Accounting for between 60-70% of Schering's earnings per share, the cholesterol franchise was by far Schering's most significant revenue driver. Schering's 2006 and 2007 Forms 10-K, among other publicly-filed documents, acknowledged that "Schering-Plough's ability to generate profits and operating cash flow depends largely upon the continued profitability of . . . Vytorin and Zetia." As Defendant Hassan stated in the Company's April 20,

2006 Form 8-K: "We are building strength through transforming and energizing our key brands. . . . ***Our cholesterol franchise [ZETIA and VYTORIN] is pivotal*** and continues to gain share in the United States and other major markets." (Emphasis added).

34. During the Relevant Period, in the absence of any disclosure of the ENHANCE results (discussed below), sales of Zetia and Vytorin skyrocketed. As of January 29, 2007, according to Defendant Hassan, Schering's cholesterol franchise was the second largest in the world. The tables below list the global sales of Zetia and Vytorin per quarter and full year (in millions, rounded), as well as the percentage increases in sales:

ZETIA	**1st Qtr. $**	**2nd Qtr. $**	**3rd Qtr. $**	**4th Qtr. $**	**Full Year $**
2006	415	474	501	535	1,925
2007	544	605	606	680	2,436
% Change (2007 vs. 2006)	+31%	+28%	+21%	+27%	+27%
VYTORIN	**1st Qtr. $**	**2nd Qtr. $**	**3rd Qtr. $**	**4th Qtr. $**	**Full Year $**
2006	371	491	517	554	1,933
2007	616	683	684	778	2,761
% Change (2007 vs. 2006)	+66%	+39%	+32%	+40%	+43%

As these tables demonstrate, total sales of Zetia and Vytorin increased every quarter from 2006 through 2007, and total combined sales of Zetia and Vytorin increased from $3.858 billion in 2006 to $5.197 billion in 2007. Prior to and throughout the Relevant Period, Defendants highlighted these results quarter after quarter while omitting and delaying any disclosure regarding the ENHANCE results.

C. The Success of Schering's Cholesterol Franchise Depended on the Company's Application of the "Lower is Better" Story to Ezetimibe

35. As Defendant Hassan stated in the Company's April 20, 2006 Form 8-K, the pharmaceutical industry at that time was facing "significant challenges," which for Schering included "the anticipated June 2006 U.S. introduction of generic versions of Merck's Zocor (simvastatin)." As Deutsche Bank analyst Barbara Ryan stated in April 2006, "[t]he driver of the [earnings per share] trajectory for [Schering] will be sales of Vytorin and Zetia and hence, ***the primary risk to the shares is a flattening out or decline in Vytorin's [prescriptions], following the launch of generic Zocor."*** (Emphasis added).

36. To combat the risk of Vytorin losing market share to generic Zocor or other statins, the Company positioned Vytorin as a product that could do what statins were designed to do, only better. A February 2005 American Heart Journal article co-authored by the Principal Investigator of ENHANCE, a colleague of his, and two employees of the Company's research and development arm (known as the Schering-Plough Research Institute or "SPRI") set forth the clinical logic for prescribing ezetimibe alone or in combination with statins:

> Lowering serum low-density lipoprotein cholesterol (LDL-C) has been shown to slow the progression of atherosclerosis and to decrease cardiovascular events and mortality; thus, lowering LDL-C is a primary objective in the prevention of coronary heart disease. Greater reductions in LDL-C produce greater reduction in events, and recent data suggest that the lower the absolute level of LDL-C, the greater the benefit, even if LDL-C levels before treatment are within the reference range. At present, aggressive lipid lowering with 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitors (statins), which inhibit hepatic cholesterol synthesis, has shown the greatest ability to lower LDL-C. This approach has become the cornerstone of treatment guidelines currently in use around the world.

> ***In some patients, however, adequate LDL-C lowering is not achieved with statins, even at maximal recommended or tolerated doses. In other patients, use of statins is limited by side effects. The addition of a second agent with a complementary mechanism of action may facilitate the attainment of such therapeutic objectives.***

(Emphasis added and footnotes omitted).[6]

37. In other words, the rationale for prescribing Zetia and Vytorin, and the basis for marketing the products to doctors and consumers, was that "lower is better." Indeed, from as early as January 1, 2007 through March 1, 2008, Schering, Merck, and M/SP ran at least 26,287 60-second television commercials, running locally and nationally, claiming that Vytorin was superior to competing statins. One example, which appeared at least 5,356 times across the United States from August, 28, 2007 through February 18, 2008, included the following language: "VYTORIN contains two medicines: ZETIA and ZOCOR. VYTORIN was . . . proven in clinical studies to lower cholesterol more than LIPITOR or CRESTOR. . . . Eat right and stay active, if that's not enough then there is VYTORIN."

38. The New England Journal of Medicine ("NEJM") reported on March 30, 2008 that more than $200 million had been spent on direct-to-consumer ("DTC") advertising for Vytorin alone in the United States in 2007. That article compared the prescription levels of Zetia in the United States against the prescription levels in Canada, where DTC advertising is not permitted. The article reported that from 2002 to 2006, among the monthly number of prescriptions for lipid-

[6] John J. P. Kastelein, M.D., Ph.D., Philip T. Sager, M.D., Eric de Groot, M.D., Ph.D., and Enrico Veltri, M.D., *Comparison of Ezetimibe plus Simvastatin versus Simvastatin Monotherapy on Atherosclerosis Progression in Familial Hypercholesterolemia: Design and Rationale of the Ezetimibe and Simvastatin in Hypercholesterolemia Enhances Atherosclerosis Regression (ENHANCE) Trial*, AM. HEART J. (Feb. 2005) ("2005 ENHANCE Article").

lowering agents, the proportion for Zetia rose from 0.2% in 2003 to 3.4% in 2006 in Canada, and from 0.1% in 2002 to ***15.2%*** in 2006 in the United States. Also in 2006, the ratio of prescriptions for statins to those for Zetia was 26:1 in Canada and 5:1 in the United States. Furthermore, in 2006, expenditures for Zetia per 100,000 persons were higher in the United States than in Canada by a factor of ***more than four***. As the article concluded, "[d]ifferences in pharmaceutical promotion in the United States and Canada may have contributed to the differential use of [Zetia]."

39. Schering made use of the "lower is better" mantra not just to market Zetia and Vytorin to doctors and consumers, but also to misleadingly market the value of its cholesterol franchise to investors:

- During Schering's Second Quarter 2006 Earnings Call on July 24, 2006, Defendant Hassan stated: "I think as you know ***lower is better*** is the other aspect which is something you should look at in terms of product mix. . . . ***[L]ower is better*** is the way the market is going . . . [and] [t]he important thing is that lower LDL has now been validated by even more outcomes trials since the joint venture was signed and this has further enhanced the value of the joint venture." During that call, Defendant Cox also stated: "[T]here is every reason to expect that the drive toward ***lower is better*** is going to continue."

- During the Morgan Stanley Pharmaceutical CEOs Unplugged Conference on January 3, 2007, Hassan stated: "And the good news is that Vytorin keeps doing well because its proposition gets better and better. ***As you look at the science that evolved, lower LDL being better, that proposition gets better and better all the time***."

- During Schering's Fourth Quarter 2006 Earnings Call on January 29, 2007, Hassan stated: "Now we will see the next wave of change with multiple generics. This is new territory, but we're encouraged because the proposition for Vytorin remains strong as ***the evolving medical science finds that lower and lower LDL is better and better***. Meantime, we're seeing the strength of Zetia continue to unfold as a distinct molecule and brand."

- During the Bear Stearns Healthcare Conference on February 27, 2007, Schering Vice President of Investor Relations Alex Kelly stated: "In terms of the data from competing products, . . . Crestor had data last year from the ASTEROID trial. It's anticipated that they'[ll] have data from the METEOR trial coming up next month at

the ACC [American College of Cardiology Conference]. It should be interesting data and will probably further prove the point of getting patients to lower LDL goals, which as I said, Vytorin gets patients to lower LDL levels than Crestor, more patients to goal than Crestor does. So to the degree that they continue to ***bring forward the story and the message that lower LDL is better***, that should also have a benefit on Vytorin and also on Zetia because Zetia can be used with any other statin. That's one of the nice features about Zetia."

- During Schering's First Quarter 2007 Earnings Call on April 19, 2007, Hassan stated: "We continue to grow Vytorin and Zetia despite the new wave of generics that has recently entered the market. ***As we have said before, physicians and their patients are following the evolving medical science; evolving medical science that is indicating that lower LDL cholesterol is better***. And now we will be extending the core of our cholesterol business into Japan." During the call, Defendant Cox added: "At last month's American College of Cardiology meeting, lowering LDL was again validated as the primary target of lipid therapy and with ***lower clearly better***, we believe this plays right into the strength of our cholesterol franchise. Only Vytorin provides more than a 50% LDL reduction at the usual starting dose and across the dosing range. More than Lipitor and more than Crestor."

- During Schering's Annual Shareholders Meeting on May 18, 2007, Hassan stated that ***"We are . . . demonstrating a special ability to get in tune with the evolving medical science.*** For example, in cardiovascular care with our innovative treatment, Vytorin, we are providing physicians and their patients with a uniquely effective means of lowering cholesterol. And this comes at a time when ***evolving medical science is saying lower and lower LDL is better***. ***So we are in tune."***

- During the Goldman Sachs 28th Annual Global Healthcare Conference on June 14, 2007, Schering Executive Vice President Thomas P. Koestler stated: "We also have a study in aortic stenosis that we are looking at as well as a study in renal dysfunction. These studies are projected out for the next two to three years before we will actually get the results on those studies. But these are nice little studies that can enhance I think the overall profile of Vytorin, particularly in those particular segments. So ***I think we are adding to the cachet, if you will, that lower is better*** and can also explore some other indications that we might see some benefit in such as aortic stenosis and patients with renal dysfunction."

- During the scripted portion of an October 22, 2007 conference call with securities analysts, Hassan stated that "***Evolving medical science continues to find that reaching lower and lower goals for LDL is better for patients and VYTORIN and ZETIA provides very good options***."

- In an Associated Press story entitled "Schering-Plough Profit Surges on Gains, but Shares Skid," dated October 23, 2007, Hassan is quoted as saying, "***The lower-is-better story continues***."

- During a November 13, 2007 Credit Suisse Healthcare Conference, Rober J. Bertolini, Schering's Controller and Vice President, stated: "There has been a slow down both in the market place and some of our share gains. . . . I think we still believe that one, the market is going to continue to grow because ***the science shows that lower is better***, so we still see market growth and we still believe we'll grow share."

- During the January 3, 2008 Morgan Stanley Pharmaceutical CEOs Unplugged Conference, Hassan stated: "***[A]ccepted medical science reinforces the fundamental point that lower LDL cholesterol is better***. . . . The lower LDL is better is a very strong proposition and a very well accepted proposition. . . . This is very, very strong clinical evidence based on many, many trials including non statins, statins, all kinds of products. ***So that is the underlying strength behind Zetia and Vytorin***. . . . [T]he reality is that the LDL by itself has such a gold standard, such a strong gold standard. ***And over the last several years, including recent years, the data that's been coming out has been pointing in that direction, lower LDL is better***. . . . ***The proposition for Vytorin is very strong, lower LDL is better."***

(Emphasis added).

II. Schering Attempted to Develop Through ENHANCE Evidentiary Support for its Claims for Ezetimibe that "Lower Is Better"

40. Critically, the authorities cited in the 2005 ENHANCE Article to support the claims that lowering LDL cholesterol slows the progression of atherosclerosis, decreases cardiovascular events, decreases mortality, and results in greater benefits with greater reductions were all medical journal articles discussing the benefits of ***statins***. Additional data on the cardiovascular benefits of statins came out before the Relevant Period: on November 12, 2003, Pfizer announced the results of the REVERSAL trial, which showed that patients taking Lipitor experienced a significant reduction in the progression of atherosclerosis compared to patients taking Bristol-Myers Squibb's Pravachol (a statin generically known as pravastatin); on November 15, 2005, Pfizer announced the results of the IDEAL trial, which demonstrated that patients who had a previous heart attack and took Lipitor to further lower their LDL cholesterol levels had significantly fewer cardiovascular events, including heart attacks, strokes or revascularization procedures, compared to patients taking Zocor; and on March 14, 2006, The

New York Times reported that in a clinical trial known as ASTEROID AstraZeneca's statin product, Crestor, had reversed the buildup of plaque in coronary arteries.

41. ENHANCE was designed to demonstrate that ezetimibe did not simply lower LDL cholesterol, but that it resulted in measurable benefits to patients. The goal was to compare the mean change in the thickness of the walls of the carotid arteries of two groups of patients with genetically-elevated cholesterol levels ("familial hypercholesterolemia") over a two year period. One group would receive the Zetia/Zocor combination in Vytorin; the other would receive Zocor plus placebo. The question was whether adding Zetia to Zocor would result in arterial wall changes in the Vytorin group that were statistically significantly better than in the Zocor group. As the authors of the 2005 ENHANCE Article put it: "The question of whether further modification of the lipid profile by the addition of a complementary non-statin agent can incrementally exert beneficial effects on atherosclerosis is of clinical importance." The metric chosen as the primary endpoint in ENHANCE was the mean change in the intima-media thickness, or IMT, of the carotid artery (with measurements taken at several locations, *i.e.*, the common carotid artery, carotid bulb and internal carotid artery for the left and right carotid arteries). As the 2005 ENHANCE Article recognized, reducing carotid artery intima-media thickness ("CA IMT" or "CIMT") has been associated with a reduced incidence of cardiovascular events:

> [C]arotid artery intima-media thickness (CA IMT) as assessed by B-mode ultrasound is predictive of angiographically determined coronary atherosclerosis and is independently associated with cardiovascular events and stroke. The risk of any coronary event increases approximately 2- to 3-fold for each 0.03 mm/[year] increase, and smaller CA IMT is associated with a reduced incidence of cardiovascular events.

Accordingly, as the article stated: "***The primary efficacy variable [of ENHANCE] is the change in ultrasound-determined CA IMT*** . . . between baseline and end point. The primary hypothesis is that CA IMT will differ between treatment groups, such that ezetimibe 10 mg/d + simvastatin 80 mg/d will be significantly more effective than placebo + simvastatin 80 mg/d in slowing or reversing the progression of CA IMT." (Emphasis added).

42. Researchers began enrolling patients in ENHANCE in August 2002, and the last patient's final visit was in April 2006. According to the (end of Relevant Period) March 30, 2008 NEJM article disclosing the full ENHANCE results, after completion of an initial run-in period during which time all dislipidemia drugs were discontinued, 720 enrolled patients had baseline measurements taken, including their LDL and other cholesterol levels and their CA IMT. Patients were then placed into one of two groups: 357 patients were assigned to receive simvastatin and ezetimibe (*i.e.*, Vytorin), and 363 were assigned to receive simvastatin plus placebo for a period of 24 months. The double-blind trial was conducted at 18 ambulatory care centers in the United States, Canada, South Africa, Spain, Denmark, Norway, Sweden and the Netherlands. Men and women between the ages of 30 and 75 diagnosed with familial hypercholesterolemia were eligible to participate.

43. Patients were to complete fourteen visits with researchers during the trial. At seven of those visits researchers took ultrasonographic measurements of patients' arteries. According to the article, two separate scans were performed within a week of each other at baseline ***and*** at 24 months to decrease any variation in measurement, to increase the statistical power, and to preserve the quality control of image acquisition, and an additional three interim measurements were taken at months 6, 12 and 18.

44. According to the NEJM article, the image database for the trial was generated and housed in the Core Echo Laboratory at the Academic Medical Center in Amsterdam, the Netherlands, and the clinical database was maintained by the sponsors (Schering and Merck). The ultrasound measurements of CA IMT in ENHANCE were, according to the 2005 ENHANCE Article, the subject of stringent quality control measures throughout the course of the trial. The article stated that "[a]ll sonographers are rigorously trained and certified before their participation in the study"; "[o]ngoing QA [quality assurance] and QC [quality control] of scans are conducted at the Core Echo Laboratory of the Department of Vascular Medicine;" and "[r]igorous QA and QC of ultrasound scans are conducted during training, certification and clinical trial phases of the study."

45. As eventually reported only in January and March 2008, over 20 months after completion of ENHANCE, the data showed that adding ezetimibe to a statin resulted in no larger beneficial effects on carotid artery intima-media thickness than simvastatin monotherapy.

III. Events in 2005 and 2006 Now Raise a Strong Inference that the Defendants Knowingly or Recklessly Concealed from Investors the Failure of ENHANCE

A. In Late 2005, Schering Statisticians Reviewed Early ENHANCE Data, Which Highly Motivated Defendants to Delay Releasing the Results

46. Although the last patient purportedly enrolled in ENHANCE in April 2004 (and therefore ended treatment by April 2006), the ultrasound images and other relevant data for hundreds of participants had been collected long before April 2006. As a result, Schering was able, in ***late 2005***, to analyze the data for early enrollers.

47. Years later, representatives of Merck and Schering explained the purported findings of these late 2005 "initial data checks" to The Wall Street Journal (in an article appearing on March 24, 2008):

> [D]uring the initial data checks, the companies got a ***jolt***: The artery-wall measurements taken when the patients entered the study were near-normal – even though they all had a genetic condition that causes unusually high cholesterol, says Schering-Plough's Dr. [Enrico] Veltri.
>
> The likely reason: Most of the patients had already been taking high doses of cholesterol-lowering statins, which had become standard treatment before the study began. Researchers hadn't anticipated the impact. ***"It was obvious to anyone that this would be a higher hurdle,"*** said Tom Musliner, a director of cardiovascular research at Merck and a member of [Schering and Merck's] clinical committee overseeing Enhance.

(Emphasis added). In late 2005 it was thus "obvious" to Defendants that the specific patient population enrolled in ENHANCE created a "higher hurdle" for demonstrating cardiovascular benefits of ezetimibe.

48. The obvious nature of that higher hurdle is borne out by comparing the CA IMT patient profile that Schering and the ENHANCE investigators appeared to have been expecting with what Schering personnel saw via the "initial data checks." The 2005 ENHANCE Article, whose authors include Dr. Kastelein, the trial's Principal Investigator, and Dr. Enrico Veltri, Vice President of Clinical Research at SPRI, states that "CA IMT is increased in HeFH patients."[7] (Footnotes omitted.) Dr. Kastelein had been involved in at least two prior clinical trials in which high-dose statins were administered to HeFH patients whose carotid artery intima-media

[7] "HeFH" refers to Heterozygous Familial Hypercholesterolemia and is the condition often referred to by the less precise terminology "familial hypercholesterolemia." Homozygous Familial Hypercholesterolemia is a much more rare and serious condition.

thickness was measured as a trial endpoint, and which resulted in journal articles that he co-authored: the ASAP trial, which resulted in a paper published in THE LANCET in 2001,[8] and another trial (the "2003 Simvastatin Trial"), which resulted in a paper published in ARCHIVES OF INTERNAL MEDICINE in 2003 (and which the 2005 ENHANCE Article cites as support for the proposition that HeFH patients have "increased" CA IMT).[9]

49. The baseline CA IMT readings in ASAP and the 2003 Simvastatin Trial are remarkably similar:

Clinical Trial	Baseline CA IMT
ASAP	0.92 ± 0.20 mm
2003 Simvastatin Trial	0.92 0.91 to 0.94) mm

50. ENHANCE, by contrast, had a mean carotid artery IMT at baseline of only 0.70 ± 0.13 mm in the Zocor cohort and 0.69 ± 0.13 mm in the Vytorin cohort. At the conclusion of the trial the measures were not much different: 0.70 ± 0.14 mm in the Zocor cohort and 0.71 ± 0.15 mm in the Vytorin cohort.

51. At his presentation of the ENHANCE results at the ACC conference in March 2008, Dr. Kastelein graphically displayed the baseline CA IMT shift seen in HeFH patients from ASAP to ENHANCE (see slide reproduced below), and posited that more effective treatments for this

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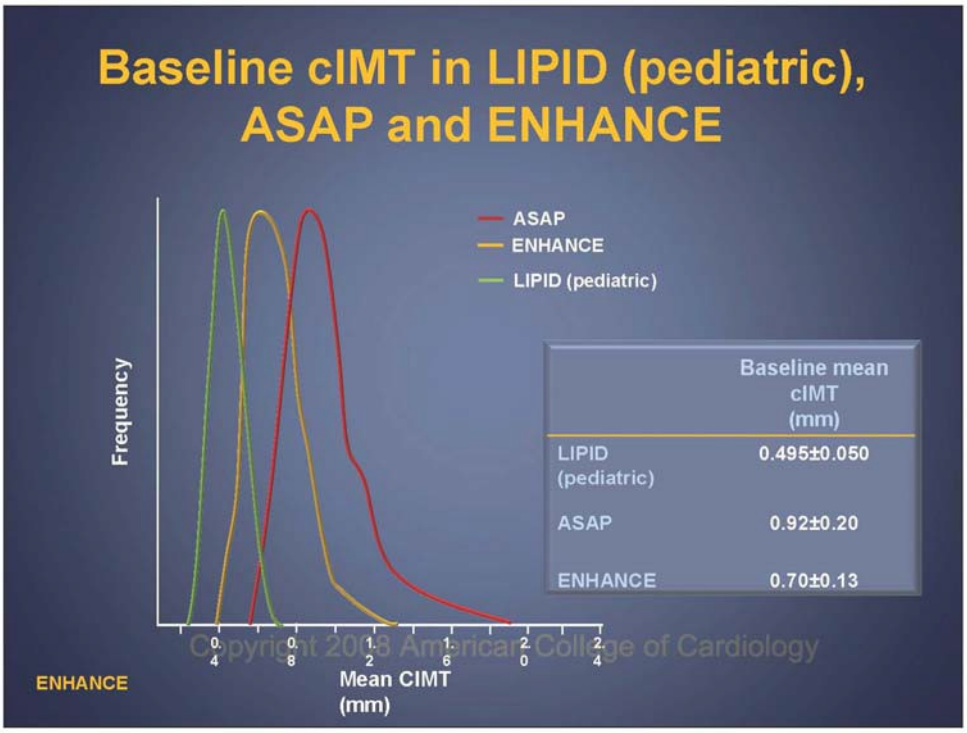
[8] T.J. Smilde, S. van Wissen, H. Wollersheim, M.D. Trip, J.J.P. Kastelein and A.F.H. Stalenhoef, *Effect of Aggressive Versus Conventional Lipid Lowering on Atherosclerosis Progression in Familial Hypercholesterolaemia (ASAP): A Prospective, Randomised, Double-Blind Trial*, THE LANCET, 357: 577-81 (2001).

[9] P.R. Nolting, E. de Groot, A.H. Zwinderman, R.J.A. Buirma, M.D. Trip, J.J.P. Kastelein, *Regression of Carotid and Femoral Artery Intima-Media Thickness in Familial Hypercholesterolemia: Treatment with Simvastatin*, ARCH INTERN MED, 163: 1837-41 (2003).

patient population prior to the commencement of ENHANCE may have contributed to the lack of any difference in treatment effect between the two groups:

> What about the population? I think the treatment of patients with FH has witnessed profound changes. And it will take you one minute to grasp this slide. The green line is the distribution of carotid IMT values in our pediatric FH population in the LIPID trial published in the *JAMA* – this. The red is actually the distribution of carotid IMT at baseline in ASAP, which was published in *Lancet*, which was done in the late 1900s. And the yellow here is actually the distribution of IMT at baseline in ENHANCE. So you can see that in the last ten to fifteen years we have shifted the entire carotid IMT distribution in familial hypercholesterolemia from very abnormal, in red, to less abnormal, in yellow. ***And therefore one could argue that because of the intensity of pre-treatment, it has become more difficult to show an effect of an addition of any other therapy.***

(Emphasis added). The slide to which Dr. Kastelein referred is as follows:



52. Even with blinded data, "initial data checks" would have revealed that the ENHANCE patient population as a whole had carotid artery intima-media thickness that was, on average, more than two tenths of a millimeter thinner than the HeFH patients in ASAP and the 2003 Simvastatin Trial were at baseline. Indeed, the ENHANCE baseline CA IMT measurements were thinner than what was seen in ASAP and the 2003 Simvastatin Trial after two years of treatment with high dose statins. Having these unexpectedly low levels of arterial plaque at the outset of the trial made it more difficult to detect the between-group difference that ENHANCE was powered to determine. Defendants concealed this fact, and the "obvious . . . higher hurdle" it represented, from investors. More importantly, Defendants were highly motivated to delay the release of ENHANCE and had the opportunity to do so, blaming purported data problems as the reason for nearly two years after the study was completed.

B. Schering Brand Team Discussions Raise a Strong Inference that Defendants Knew or Recklessly Disregarded, by the Summer of 2006, that ENHANCE Would Not Provide Positive Results

53. In April 2006, three-and-one-half years after patients began enrolling in ENHANCE, researchers completed the final patient visit. According to the Consolidated Class Action Complaint in the Schering-Plough Class Action, CW 1 a Senior Medical Director in charge of Schering's Cardiovascular Therapeutics from November 2004 until September 2006, Schering knew by the summer of 2006 that ENHANCE would not provide positive results. CW 1 interacted with Schering's Brand Team on a daily basis regarding Zetia and Vytorin. Leadership for the Brand Team included Sean McNicholas, Ray Russo, Michael McCann, Michael Matin, Eric Cox, Steven Morales, and Denise Foy. According to CW 1, Russo, Matin, Morales, and Foy were among the members of the Brand Team most involved and familiar with the ENHANCE study.

54. Despite the fact that the ENHANCE data was purportedly blinded, updates regarding ENHANCE were shared in quarterly Brand Review Meetings that CW 1 attended and which were conducted by Defendant Cox. CW 1 stated that there was a quality control assessment of ENHANCE data done in late 2005 to early 2006. This is consistent with the above-quoted March 24, 2008 Wall Street Journal article, in which representatives of Schering, Merck, and M/S-P admitted that "Dr. Kastelein's team began sending complete measurements from the first group of patients" in "late 2005" following which statisticians "began routine checks to make sure the data were in order." According to CW 1, by the spring or summer of 2006, it was clear that there were real problems with ENHANCE, and in the summer of 2006, the Brand Team held meetings to discuss what they would do if the ENHANCE results were negative, particularly because it was unlikely that they were going to obtain meaningful results from ENHANCE and, by contrast, Schering's competitors likely were going to continue reporting positive results from their drug trials. CW 1 stated that in the summer of 2006, his team "knew that there were not going to get any good news from" ENHANCE. CW 1 stated that those persons within Schering who were associated with the cholesterol franchise would know this information. According to the Consolidated Class Action Complaint in the Schering-Plough Class Action, and as explained more fully below, the individuals at Schering most familiar with the Schering cholesterol franchise and ENHANCE included Defendants Hassan and Cox, Schering's Chief Financial Officer ("CFO") during the Relevant Period, Robert J. Bertolini ("Bertolini"), Schering's Controller and Vice President during the Relevant Period, Steven H. Koehler ("Koehler"), the members of the Brand Team, Dr. Toni Bransford (SPRI Clinical Project Director, Cardiovascular-Global), Vice Presidents of Clinical Research Drs. Veltri and Strony, and Statistician Bo Yang.

IV. Defendants' Actions in 2007 Raise a Strong Inference that They Knowingly or Recklessly Concealed from Investors ENHANCE's Failure to Provide Positive Results

A. Despite the Bots Report's Conclusion in January 2007 that the Quality of the ENHANCE Data Was "Fine," Schering Failed to Publicly Disclose the ENHANCE Results

55. In January 2007, members of the Schering ENHANCE study team (including Dr. Toni Bransford, Medical Director in the Cardiovascular Medical Institute, and Dr. John Strony, Medical Director and Project Physician for Zetia/Vytorin) hired Dr. Michiel L. Bots, M.D., Ph.D., Associate Professor of Epidemiology at the Julius Center for Health Sciences and Primary Care of the University Medical Center of Utrecht in the Netherlands, as an independent consultant to prepare a report concerning purported problems with the data collected in ENHANCE. Schering and Dr. Bots set up three meetings in Amsterdam at the Core Echo Laboratory to address Schering's purported concerns, one on January 16, 2007, and two on January 18, 2007.

56. Dr. Bots's report, eventually made public by Congress (the "Bots Report"), states that its purposes were to: (i) determine whether individuals collecting the ENHANCE data had read the ultrasound images according to the ENHANCE study protocol; and (ii) address supposed data "outliers" in the form of unexpectedly large CA IMT (or "CIMT") differences between patient visits. The Bots Report also addressed any issues of missing data, or "missingness" in ENHANCE.

57. As Dr. Bots soon discovered, there were in fact no problems with the ENHANCE data that would justify the extended delay of its results. The Bots Report, dated January 26, 2007, concluded that: (i) researchers had read the ultrasound images in accordance with the

ENHANCE protocol; and (ii) "***the CIMT data [were] fine***; *i.e.*, no better, no worse than what [had] been reported in the literature [*i.e.*, in other similar studies of CIMT]." The Bots Report also alluded to an unidentified Schering statistician who had consistently found problems with the data. However, Dr. Bots concluded that those findings were of "little concern."

58. To address the question of whether researchers followed the ENHANCE protocol in collecting the data, the Core Laboratory demonstrated to Dr. Bots at the January 16, 2007 meeting how the measurements were taken. Dr. Bots concluded that, "[t]hese were indeed done in a manner that was described in the protocol." And, as restated twice more in his report: "The CIMT measurements seem to be done according to the procedures outlined in the protocol."

59. As to the question of outliers, Dr. Bots made several points:

> [F]irst, the reproducibility of the data needs to be evaluated. This included reproducibility data from visits 3-4 [the first two measurement visits] and from visits 13-14 [the last two measurement visits] and indicated that the reproducibility of CIMT (the entire process including variability due to imaging and reading) is excellent in this study. The same applied for the mean absolute CIMT difference and the standard deviations. These data are well in line with studies that have been published in the literature. ***Based on these findings there seems to be little concern regarding the validity and precision of the data.***

(Emphasis added). Dr. Bots thus concluded that the reproducibility of the data was "excellent," as was the mean absolute CIMT difference and the standard deviations, and that therefore there was "little concern regarding the validity and precision of the data." Particularly important was Dr. Bots's conclusion that the "variability due to imaging and reading" was "excellent." In response to a Schering statistician's concerns about results "beyond biological variation," Dr. Bots pointed out that the variation strongly resembled that in another CIMT study.

60. According to the Bots Report, in response to the purported concerns of a Schering statistician, the Core Laboratory then re-evaluated all of the images of visits 3-4 (the first two measurement visits) and 13-14 (the last two measurement visits) that had a CIMT value that was 50% or more different. Next, the statistician evaluated how the reproducibility based on the original data changed when the "corrected" outlier data were used. As Dr. Bots noted, "This improved in particular the standard deviation of the mean differences. ***Yet, the improvement was very modest***." (Emphasis added).

61. The Bots Report also addressed the subject of missing data. For the common carotid segment, CIMT data was missing for 4% of the participants; for the bifurcation segment, CIMT data was missing for 12% of the participants; and for the internal segment, CIMT data was missing for 12%. The Bots Report described this level of missingness as being "in line with observational studies." Moreover, as to whether the missing data affected the CIMT estimate at the patient visit, Dr. Bots found that: "Missingness may affect the CIMT value. ***Yet, the current statistical models that are used in the analysis of CIMT trial data do appear to take care of that in an adequate manner***." (Emphasis added).

62. Ultimately, the Bots Report concluded that "the reproducibility study showed that the CIMT measurements have been done in a consistent manner, leading to reproducibility findings that compare well with that of published studies from other multicenter randomized trials." Likewise, regarding the missingness point, Dr. Bots concluded that "the data are fine."

63. Despite these conclusions, Schering purportedly remained dissatisfied, and sought suggestions as to how to improve the data. Bots made such suggestions, but ultimately felt that they were unnecessary:

> "[It is] important . . . to realize that the above mentioned activities might reduce measurement volatility to some extent. ***Since this is expected to involve only a small number of the measurements, the expected effects on variability are likely to be modest***. Again, randomization [sic] protects against bias the estimate of the difference between treatment arms.

(Emphasis added). In short, on January 26, 2007, Dr. Bots reported to Schering that the ENHANCE study data were "fine," and that to the extent there were data problems, they were insignificant, had minimal impact on the study results, and were well within the range of what is considered to be normal for such studies. Moreover, Dr. Bots found that any proposed changes to the study would have only "modest" effects on variability.

64. Indeed, the Bots Report demonstrated that Schering had no valid basis to delay publication of the ENHANCE results. Dr. Bots advised Schering of what it already knew or recklessly disregarded for months: that the ENHANCE results – which were financially catastrophic to Schering – were in fact scientifically sound. In the months that followed, the Company knowingly or recklessly created pretexts to delay release of the results, if not discard them altogether.

65. Indeed, it would be ***ten months*** after the Bots Report confirmed what the Company already knew before Schering convened an expert panel to revisit the issues Bots addressed, as discussed further below, and ***twelve months*** after the Bots Report that the study results were finally released (and then only as a result of pressure by Congress).

B. The Posting of ENHANCE Results on the CaféPharma Website as Early as March 2007 Supports a Strong Inference of Scienter

66. CaféPharma (www.cafepharma.com) is a "website for pharmaceutical sales professionals and those interested in the pharmaceutical industry." Pharmaceutical sales representatives and

other industry professionals visit CaféPharma to exchange information about pharmaceutical companies and the products they sell, their competitors, and other developments affecting people who work in the industry. The website includes scores of pharmaceutical company "boards," ranging from Aai Pharma to Zygogenetics, which function like virtual bulletin boards, allowing visitors to the website interested in exchanging information about a pharmaceutical company to visit the company board, read comments posted on the board, or post their own comments on it.

67. The posting of non-public ENHANCE study results on the CaféPharma website as early as March 2007 (which were publicly corroborated only after the full release of the ENHANCE study data in March 2008), creates a strong inference that individuals inside the Company were aware of or recklessly disregarded the ENHANCE results more than one year before they were released by the Company.

68. Beginning in March 2007, dozens of posts about ENHANCE began appearing on the Schering board at CaféPharma. Certain of the anonymous posts claimed to know the results of ENHANCE, and included specific, non-public details that only Schering insiders would have known at the time, and which were later revealed to be correct. This supports the strong inference that Defendants knew the results, either because analyses were performed on blinded data that essentially ruled out the possibility of a statistical difference between the two groups of patients (discussed further, *infra*, at ¶¶ 194-201), or because the ENHANCE results had been un-blinded within the Company. The CaféPharma posts further support the strong inference that by no later than March 2007, Defendants were aware of or recklessly disregarded the ENHANCE results.

69. Importantly, the CaféPharma posts concerning ENHANCE in 2007 did not give ordinary investors any reason to investigate further; the posts were anonymous, which, absent confirmation of their accuracy by the Company or other independent, reliable third-party sources, called into question their validity. They did not have sufficient indicia of reliability to be material to reasonable investors at the time of their posting. That changed, however, when Schering and M/SP disclosed the actual results of ENHANCE in early 2008, and those results confirmed the claims made on CaféPharma approximately one year earlier. The actual ENHANCE results reported in 2008, when compared to the earlier CaféPharma posts, now create the strong inference that the adverse ENHANCE results were known within Schering long before they were publicly disclosed.

70. On March 7, 2007, under the subject heading, "ENHANCE," the following post appeared on the Schering board at CaféPharma: "Hey, whatever happened to the ENHANCE study for Zetia that was supposed to be at ACC [The American College of Cardiology Conference in March 2007]? One of my docs told me that it wasn't anywhere on the agenda at the meeting, but METEOR (Crestor) was. Is there some problem?"

71. On March 13, 2007, a post replied: "[H]ave a buddy at SPRI. ***He says that the study is a bust***. ***Adding Zetia to already maxed-out statin is useless***." (Emphasis added). The March 13 post is now noteworthy for several reasons. First, it correctly identified SPRI – Schering-Plough Research Institute – as the source of the ENHANCE study. Second, it correctly identified that the study tested a comparison of Vytorin (Zetia plus simvastatin) versus simvastatin. In addition, as noted in the post, adding Zetia to a treatment population "maxed out" on statins was useless. In fact, the post is entirely consistent with the across-the-board failure of ENHANCE later

described by Dr. Kastelein in March 2008: Vytorin had ***"no result – zilch. … In no subgroup, in no segment, was there any added benefit"*** on the patients' atherosclerosis. This post supports a strong inference that individuals within Schering were aware of and discussing the results of ENHANCE (*i.e.*, "that adding Zetia to already maxed-out statin is useless") or recklessly disregarded those facts no later than March 13, 2007 – almost one year before the Company released the partial results. While the import of these posts (and the additional CaféPharma posts set forth below) could not be appreciated by the media or the analysts covering Schering (who made no mention of them) when the posts appeared, or by the market (Schering's stock price rose), the same cannot be said for the Schering insiders who knew the ENHANCE results and remained silent.[10]

C. Defendant Hassan's April 2007 Downplaying of the Importance of ENHANCE Supports a Strong Inference of Scienter

72. Defendant Hassan began deliberately downplaying the importance of ENHANCE and discrediting its results as early as April 2007, if not earlier, including, for instance, on the Company's April 19, 2007 first quarter 2007 earnings conference call. Tim Anderson, an analyst at Prudential Equity, asked Hassan, "Your first big kind of quasi-outcomes trial is coming up on VYTORIN, which is ENHANCE, and I have not heard you talk much about that despite that trial and all those results almost being in hand. It seems like they could be fairly important to [the]

[10] For instance, the price of Schering common stock rose or was flat in the days following the Wednesday, March 7, 2007 and Tuesday, March 13, 2007 posts, discussed above. The day after the March 7, 2007 post, the price of Schering common stock closed $0.28 cents higher than it had the day before the post. The day of the March 13, 2007 post, the price of Schering's common stock closed at $23.28, only $0.67 cents lower than it had closed the day before (at $23.95). By Wednesday, March 21, 2007 Schering's common stock price had increased from its March 12 price, closing at $24.43.

VYTORIN franchise. I'm wondering if you are at all worried about the outcome of this trial in terms of what it shows?" Hassan replied:

> First, I think we've already discussed on previous occasions that the data analysis is ongoing for the ENHANCE trial. That as you know is a surrogate market trial in a ***very special population with very special doses***. There is a much larger trial called the IMPROVE-IT trial which is more of an outcomes trial. So one has to look at the overall mix of the data. The overall regression curve in terms of LDL, lower LDL, is better, is being proven in numerous studies, so we are pretty confident about the overall pattern of data for VYTORIN.

(Emphasis added). In this statement, Hassan made a vague reference to the fact that the ENHANCE study involved "a very special population." Hassan, however, failed to disclose to the market what Schering had already known or recklessly disregarded – that ENHANCE had failed to demonstrate a benefit of Vytorin versus simvastatin. As set forth below (*see* ¶ 117), Hassan made similar statements thereafter, including on January 3, 2008. Statements like these – when viewed in light of the Company's later disclosures of the ENHANCE results and consistent with the other facts set forth herein – raise a strong inference that Hassan downplayed ENHANCE in this fashion because he was aware of or recklessly disregarded its negative results.

D. Additional Postings of Non-Public ENHANCE Results on the CaféPharma Website During the Summer and Fall of 2007, and Internal Schering Email in the Summer of 2007 Raise a Strong Inference of Scienter

73. Over the course of the summer, and into the fall of 2007, additional posts appeared on the CaféPharma website revealing specific, detailed, non-public (and, at the time, unverifiable) accounts of the ENHANCE results. As is now clear, the information contained in these posts was consistent with the actual ENHANCE results. Given Defendants' familiarity with the site and the non-public information being posted (the veracity of which was only revealed to investors after the ENHANCE results were disclosed in 2008), this supports a strong

inference that individuals at Schering were aware of or recklessly disregarded those results. In addition, internal Schering email in the summer of 2007 (first disclosed to the public on April 18, 2008 in connection with Congressional investigations into the delayed release of the ENHANCE results) demonstrate that Schering insiders knowingly or recklessly had delayed the public release of ENHANCE results and took control of the release of the ENHANCE results from the study's Principal Investigator, Dr. Kastelein.

74. On June 3, 2007, a post appeared on the CaféPharma website under the heading, "Re: What happened to ENHANCE?" The post stated: "Still not released! Heard it crashed and burned!" The next day, under the same subject heading, another post stated: ***"NO difference in the primary endpoint (change in CIMT from baseline) between simva+zetia and simva+placebo, and there were higher rates of liver problems in the simva+zetia group."*** (Emphasis added).

75. Not only did both posts get the result right, the latter was also correct in noting that Vytorin patients had "higher rates of liver problems." As first disclosed in March 2008, the percentage of patients forced to discontinue the trial due to elevated liver enzymes was higher in the Vytorin cohort (2.8%) than in the Zocor cohort (2.2%). Again, unbeknownst to investors at the time, these statements were accurate, reached the same conclusions announced by the Company approximately seven months later, and demonstrate that the results of ENHANCE were known or recklessly disregarded inside the Company long before the Company released them.

76. In July 2007, senior Schering researchers received email from Dr. Kastelein, the ENHANCE Principal Investigator, informing them that there was no good reason to delay

publication of the results. On July 6, 2007, Dr. Kastelein sent the following email to Dr. John Strony at Schering:

> Dear John
>
> ***[I]s it correct that SP has decided not to present at AHA [the American Heart Association conference from November 4-7, 2007], but to await the two other, completely unvalidated, endpoints, which analysis is going to take us straight into 2008 ??!!??*** If this is true, SP must have taken this decision without even the semblance of decency to consult me as PI of the study. ***I can tell you that if this is the case, our collaboration is over and I will take the appropriate steps to get in touch with the editors of major Journals as well as with the FDA. This starts smelling like extending the publication for no other then [sic] political reasons and I cannot live with that.*** This is the second day of a long overdue holiday after a terrible year, thank you very much for yet another terrible chapter of this trial.
>
> John

(Emphasis added).

77. In response, Dr. Strony offered an inadequate explanation of the delay, which emphasized purported problems with the data, seven months after the independent analysis contained in the Bots Report had concluded there were no such problems. Dr. Strony stated in response to Dr. Kastelein:

> The timeline for the reading of the femorals alone has been a movingtarget [sic]. First it was 8 weeks, then 12, and then 16. This is under the assumption of having 4 readers. However, one of the four has failed qualification and now we are down to three. If all runs smoothly (whichhas [sic] never happened in ENHANCE) we are told it will take 17 weeks for the primary readings. Don't forget the querying process and clean-up which is still not factored . . .

78. In response, Dr. Kastelein emailed Dr. Strony on July 7, 2007, this time copying Dr. Veltri, SPRI's Group Vice President of Global Clinical Development:

> I have been travelling half the globe in the last 6 months to a number of large and important meetings at the strong wish of Merck to chair them or to present ezetimibe data. At every single one of them I was cleared to say that ENHANCE would be presented by me at AHA. ***There is no reason whatsoever to include femorals; you will be seen as a company that tries to hide something and I will be perceived as being in bed with you!***
>
> John

(Emphasis added).

79. After receiving another rationalization for the delay, this time from Dr. Veltri, Dr. Kastelein responded with an email on July 13, 2007 (again copying Strony):

> Dear Rick,
>
> I am glad you took the trouble of providing me with such a long answer. The raging part of my former emails comes from an enormous amount of frustration and ***a feeling that I have no control whatsoever on anything that relates to ENHANCE.*** As you know, in my normal state of mind, I am a controlled individual and I am not hard to work with. ***However, in all my previous experiences as a member of a Steering Committee or as a PI [Principal Investigator], I felt I was in control. With ENHANCE, that is totally the opposite.***
>
> ***The database is at SP***, consultants like Gene Bond are in my opinion impossible to work with and never agree with me, Bo Yang has made several crucial mistakes on the way that cost us 9 months, Eric is a nightmare to work with in terms of organization and I can go on and on. The last example of this "never working with me" is the fact that you have decided to withdraw the abstract. This is not necessary. You could have sent in an empty abstract that as my friends at AHA tell me can be filled with data one week before AHA itself and if you were too late, you simply withdraw it. One phone call to me would have cleared all of this. This is exactly what I have done with Pfizer for the Torcetrapib latebreakers at ACC this year. The data were ready 3 days before ACC.
>
> Also, I am constantly under pressure from Merck to plan all sorts of activities, before, at and after AHA. ***Because I !! will be the one who have to stand up and present and defend the data, and I***

> ***would deeply appreciate being involved again and not just simply at the end of a long decision line***.
>
> Regards, John

(Emphasis added).

80. According to the Consolidated Class Action Complaint in the Schering-Plough Class Action, Confidential Witness 2 ("CW 2"), who was a consultant for Schering on ENHANCE and who worked directly with researchers in Amsterdam for approximately four to five years regarding quality control of the ultrasound imaging, among other things, corroborates that the ENHANCE data was in Schering's control. CW 2's expertise concerned how to measure, examine and interpret data. CW 2 primarily spoke to the people directly responsible for the ultrasound and image readings at the center in the Netherlands and frequently emailed and participated in conference calls with Dr. Strony. CW 2 reports that s/he did not have direct access to any of the databases, and when information was needed on how individual sonographers or readers were performing, the relevant data needed to be requested from Dr. Strony. Indeed, according to CW 2, Schering was in control of the ENHANCE database and code from at least as early as 2006, and Schering performed the analysis.

81. On July 19, 2007, the following post appeared on CaféPharma, under the subject heading: "ENHANCE-Zetia 10/Simva 80 NOT better than simva 80/placebo!!!" The post continued:

> Now we know why this was pulled from ACC!!! [the American College of Cardiology Conference held on March 24-27, 2007 in New Orleans] We've been living off the LDL lower is better story versus statins alone since launch [of Vytorin and Zetia on the market]. This is the first trial with a clinically meaningful end[p]oint (carotid IMT) and shows that ***adding Zetia to high dose GENERIC statin provides no real benefit***. By inference, it suggests that Vytorin is really no better than the simva component alone, too. Based on this, it's easy to predict that IMPROVE-IT

> may very well be a bust as well. The only saving grace of that trial is that [it] is so large (10,000 pts) that even very small differences may still be statistically significant-but not really clinically significant. Economically-speaking, generic simva is so cheap now (and getting cheaper) that adding Zetia or using Vytorin will have to provide a wide margin of benefit in order to make up for cost differences. ***ENHANCE shows us that there is and will be no wide margin of benefit***. We're screwed once MCOs [managed care organizations] and PBMs [pharmacy benefit managers] figure this out. Better get those rebates ready!

(Emphasis added). The July 19, 2007 post accurately stated what the Company finally disclosed to the market only in early 2008 – that there was no statistically significant difference in treatment arms in the ENHANCE study. Calling ENHANCE "the first trial with a clinically meaningful end[p]oint (carotid IMT)" (*i.e.*, something other than a surrogate endpoint like LDL cholesterol) the post correctly pointed out that adding Zetia to statins provided "no real benefit." The reference to the study being "pulled from ACC" was to the decision not to proceed with the presentation of the ENHANCE results at the ACC Conference in March 2007. The statement that "We've been living off the LDL lower is better story" referred to the refrain, repeatedly stated by the Company in investor conference calls and elsewhere, that ezetimibe, when combined with statin therapy, provided benefits beyond those available from statin monotherapy. The Company continued to repeat this refrain, even though, unbeknownst to investors, ENHANCE called the hypothesis into serious question. Additionally, the post identified what the Company feared and why it failed to release the results – that ezetimibe's failure to demonstrate cardiovascular benefits would not justify the high cost of Zetia and Vytorin in comparison to less expensive generic statins. The post also correctly noted that IMPROVE-IT – another clinical trial comparing Vytorin and Zocor on their ability to prevent heart attacks – was not yet completed as of July 19, 2007, and discussed the potential outcome of that study as only a prediction.

82. Five days later, on July 24, 2007, another post on CaféPharma responded to the foregoing post:

> I think the time delay is because they are stalling in order to do 2 things: 1) datamine the trial to try to find some secondary or tertiary endpoint analysis that looks positive to some degree to offset the primary endpoint not being met, and 2) develop a counter-strategy to spin the results and/or discredit/disavow the trial (*i.e.* point out limitations in study design, the endpoint, etc). By itself, this trial won't torpedo the whole thing because there are too many people who think that carotid IMT isn't an ideal endpoint, and they'll come out with some BS about "having to wait until the results of IMPROVE-IT before we have the definitive answer". Thye [sic] should be shitting bricks over in R&D and Marketing, beacuse [sic] the ARBITER-1 trial (an IMT study) perfectly predicted both the REVERSAL and PROVE-IT trials. IMPROVE-IT is 10,000 patients – any trial requiring that large of an N indicates that the absolute difference between [sic] the 2 comparators is expected to be quite small. If ENHANCE indeed is negative, and I have heard form [sic] sources close that it is, then IMPROVE-IT is definitely at risk. ENHANCE will hurt, and it may slow us down, but IMPROVE-IT may cause the whole thing to a [sic] backslide.

This post is in many respects a roadmap for how Schering handled the eventual public release of the ENHANCE results. As discussed further below, on November 19, 2007, four months after this post appeared, Schering announced (but later abandoned) its intent to change the primary endpoint of the study (a highly unusual break from scientific protocol). Defendants also had already begun implementing the counter-strategy of discrediting and disavowing the trial by minimizing its significance in favor of IMPROVE-IT. The larger point made by this post is that results in a trial measuring IMT may foreshadow results in larger trials measuring clinical outcomes because positive results seen in an early IMT trial with Lipitor (the ARBITER-1 trial) "perfectly predicted" additional successes for Lipitor in the REVERSAL and PROVE-IT trials.

83. On September 20, 2007, another post on CaféPharma in the "Re: ENHANCE" thread appeared. That post stated:

> One of my docs is a very good friend of the study PI [Principal Investigator] overseas. ***I'm told that the study IS negative in that there is absolutely no difference in carotid IMT between simva 80+placebo vs simva 80+Zetia 10. Although Zetia did lower LDL-C as expected, it did nothing else of any value. So much for "lower is better"! Apparently, the PI and the company have been arguing back and forth about how/when to release the info. PI wants to report, but company keeps blocking/delaying.*** We're pretty well-screwed if what is essentially max dose Vytorin is no better than max dose generic simva!!

(Emphasis added). This post correctly identified material facts that the Company would not reveal for months after it was posted, namely that: (i) the study was negative; (ii) there was no statistically-significant difference between 80 milligrams of simvastatin plus placebo and 80 milligrams of simvastatin plus 10 milligrams of Zetia; (iii) Vytorin did lower LDL cholesterol as expected but it did nothing else of value; and (iv) (as confirmed by the documents later made public by Congress) the ENHANCE Principal Investigator, Dr. Kastelein (overseas at the Academic Medical Center, Amsterdam) and the Company were arguing internally about when and how to release the ENHANCE results, with Dr. Kastelein wanting to report and the Company "blocking and delaying." Not until the January 2008 release of the ENHANCE data and the April 2008 public release of Dr. Kastelein's emails by Congress discussed above could investors have verified the contents of this post.

84. On November 14, 2007, a post indicated that the investigators had been discussing the negative study results:

> ***[W]ord of mouth from investigators involved in running the trial is that it is a negative study.*** We and Merck both talked up this study publicly a bunch before the results were known internally,

> now both are stone cold silent. The study was first supposed to be presented at AHA [the American Heart Association meeting in] 2006, then ACC 2007, and now both ESC [the September 1-5, 2007 European Society of Cardiology Congress] and AHA are passed this year with not a peep. You do the math.

(Emphasis added).

85. When read together, and in light of the Company's subsequent disclosures, it is now clear that these posts were more than just speculation. They were highly-informed postings of accurate ENHANCE results, sourced from both inside SPRI and study investigators, which raise a very strong inference that within Schering the results of ENHANCE were already known or recklessly disregarded.

E. Defendants Concealed the ENHANCE Results During the August 2007 Public Offering of Schering Common and Preferred Stock

86. In August 2007, sixteen months after ENHANCE had ended, Schering conducted two securities offerings on behalf of Schering (collectively "the Offering") through which the company raised a total of approximately $4.08 billion. Through the Offering, Schering sold $1.58 billion of its common stock and $2.5 billion of preferred stock to the investing public without disclosing the results of ENHANCE. Schering conducted the Offering in large measure to finance the Company's acquisition of Organon Biosciences N.V. ("Organon"), a Netherlands-based pharmaceuticals company that Schering expected to help fill the gap in its late-stage drug pipeline (especially in light of the yet undisclosed ENHANCE results).[11] In the Company's

[11] On September 7, 2006, the shareholders of Akzo Nobel, a Netherlands-based Fortune Global 500 industrial company, approved that company's split into two entities – Akzo Nobel, active in coatings and chemicals; and Organon, active in pharmaceuticals. At that time, Akzo Nobel planned to sell approximately 20-30 percent of the Organon entity through an IPO on the Euronext Amsterdam exchange in early 2007. However, on March 12, 2007, Schering surprised investors (who had been awaiting the announcement of a planned Organon initial public offering, which valued the Organon business at approximately $10 billion) by agreeing to purchase

March 2007 announcement of the purchase, Defendant Hassan specifically referred to the acquisition of Organon as "fill[ing] a gap in our late-stage pipeline by adding five compounds in Phase III development and a number of promising projects in Phase II development."

87. On March 12, 2007, Morgan Stanley reacted positively to the Organon acquisition, finding that the deal "further diversifies [Schering's] risk away from Vytorin and Zetia." Citigroup echoed this sentiment in a March 13, 2007 analyst report stating that the acquisition "will allow SGP to diminish its reliance on its cholesterol franchise (with several competitive threats on the horizon)." Although Citigroup noted the competitive threats to the cholesterol franchise, it still estimated Vytorin would have "global sales of approximately $4.1 billion by 2011."

88. On or about August 2, 2007, Schering commenced the Offering by filing the Registration Statement on Form S-3ASR with the SEC, with an effective date of the same day. The Offering included: (1) the August 9, 2007 Common Stock Offering of 57,500,000 shares of common stock at $27.50 per share; and (2) the August 10, 2007 Preferred Issuance of 10,000,000 shares of 6.00% mandatory convertible preferred stock at $250 per share. The Offering Documents[12]

Organon for $14.4 billion in cash. In the words of Mark van der Geest, an analyst at Rabo Securities in Amsterdam: "This came as a complete shocker and the price [for Akzo Nobel's shareholders] is phenomenal."

[12] The Common Stock Offering was marketed and sold to the public through the materially misstated Registration Statement, and prospectus supplements dated August 2, 2007 and August 9, 2007 and filed with the SEC pursuant to Securities Act Rules 424(b)(3) and 424(b)(2), respectively (the "Common Stock Prospectus"; together with the Registration Statement, the "Common Stock Offering Documents").

The Preferred Stock Offering was marketed and sold to the public through the materially misstated Registration Statement, and prospectus supplements dated August 2, 2007 and August 9, 2007 and filed with the SEC pursuant to Securities Act Rules 424(b)(3) and 424(b)(2),

discussed in detail the importance Zetia and Vytorin played in Schering's business and financial results, yet they failed to disclose the results of ENHANCE, thereby rendering the Offering Documents materially false and misleading.

89. Defendants were motivated to conceal the ENHANCE results to artificially inflate the Company's stock price, which significantly contributed to the success of the Company's $4.08 billion Offering. If Schering had disclosed the ENHANCE results prior to the Offering, or prior to its acquisition of Organon, Schering's share price would have dropped drastically, thereby endangering the success of the Offering, the acquisition of Organon, and Schering generally.

90. Shortly after the Offering, on November 19, 2007, Schering announced the finalization of the Company's acquisition of Organon. As Hassan described in the press release: "By bringing together complementary businesses, we will be growing even stronger and even better in our people, products and science. . . . ***The promise of this combination is profound***."

F. Schering Convened a Panel of Outside Consultants and Publicly Misrepresented that the Panel Had Recommended a Change of ENHANCE's Primary Endpoint

91. Schering convened a panel of consultants on November 16, 2007 – eleven months after the Bots Report and four months after Dr. Kastelein rebuked the Company for unwarranted delays – to yet again discuss supposed problems with the ENHANCE data. The expert panel consisted of: J. Robin Crouse, M.D., of Wake Forest University; James Stein, M.D., of the University of Wisconsin; David Orloff, M.D., at Med Pace; Greg Evans, M.S., of Wake Forest

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respectively (the "Preferred Stock Prospectus"; together with the Registration Statement, the "Preferred Stock Offering Documents").

University; and Dr. Bots. Eleven Merck and Schering employees were also in attendance at the meeting, including Drs. Strony and Veltri. Dr. Kastelein, however, was not in attendance.

92. Over one month after the expert meeting, on December 19, 2007, Schering drafted and Dr. Strony circulated to participants "minutes" of the November 16, 2007 expert meeting, after Schering had represented to the meeting participants at the start of the meeting that there would be no meeting minutes or transcript. The comments on the draft "minutes" by one of the meeting's panel members and attendees, Dr. Stein, of the Division of Cardiovascular Medicine at the University of Wisconsin, were subsequently made public in connection with the Congressional investigations into the delayed release of the ENHANCE results, and demonstrate that the Company: (i) hand-selected the data that the experts viewed; (ii) tried to hide this fact; and (iii) tried to impute a conclusion to the panel that the panel did not reach, namely, that the Company should change the pre-specified primary endpoint of the study.

93. On December 19, 2007, Dr. Strony asked Dr. Stein to comment on the draft "minutes" of the November 17, 2007 meeting, which Dr. Stein did in a December 21, 2007 email. Regarding an entry in the draft minutes that stated: "[T]he Panel members were granted unrestricted access to the blinded image data base," Stein responded:

> I believe that this sentence is an overstatement. We had approximately 6 hours to work so the number of images we were able to review was limited. ***They may have been 'available' but they could not be reviewed meaningfully because of time constraints. We reviewed, at most 50-75 images [out of approximately 30,000 images] and those only were images that the company chose to show us.*** I recall that I and Dr. Evans added the qualification that ***our conclusions were based on the images we saw, and they were not a randomly selected set of images, thus they were potentially biased because they were selected by the company to illustrate certain points.*** Therefore, we can't exclude

> the possibility that we'd have different conclusions if we saw the rest of the images.

(Emphasis added).

94. Thus, in what was supposed to be an effort to obtain neutral, expert feedback about the ENHANCE data (eleven months after it had already received such feedback from Dr. Bots), the Company itself hand-selected "50-75" out of 30,000 ultrasound images to show the expert panel, and then attempted to misstate the minutes from the meeting to suggest that the panel was granted "unrestricted access" to the data. In fact, the panel was granted only restricted access to the ***worst data***.

95. Materials prepared for the November 16, 2007 meeting by Drs. Strony and Veltri, Schering's Director of Statistics, Ramachandran Suresh, and Schering's Associate Director of Statistics, Bo Yang, also presented to the independent panel a purportedly dire picture of the ENHANCE data in an apparent effort to further delay or modify the release of the results. One slide included the statement, "[e]xisting data is not statistically analyzable," and under the heading "Statistical Issues," another slide stated, "[t]here is [a] tremendous risk analyzing this data." The veracity of these statements, however, is severely undermined by the fact that Schering (under pressure from Congress) released preliminary results of ENHANCE (based on this same data) only two months later.

96. The draft minutes also stated that, "The common carotid artery (CCA) provides the most reliable and consistent measurements in IMT studies with the least level of missingness or implausible readings. Therefore, the CCA is now commonly considered the most reliable endpoint. Thus the CCA should be elevated to become the primary study endpoint." In response to this statement, Dr. Stein wrote:

> ***This was not a conclusion of the meeting***. We stated that in regard to this (ENHANCE's) specific data set, with its imaging and measurement problems, the measurements of the CCA are the most valid segmental measurements. In this content [sic], 'valid' means most likely to reflect the scientific truth – the real measurements of the carotid IMT. We said the company could 'consider' making the CCA measurement the primary endpoint.

(Emphasis added.)

97. Dr. Stein further noted:

> [T]he tone of these conclusions makes it seem as [if] these were strong, unanimous, scientific recommendations, rather than opinions with varying degrees of enthusiasm from panel members and varying degrees of scientific justification. ***Indeed, the conclusions were made by the companies, not by us***.

(Emphasis added.)

98. These comments reveal that Schering attempted to distort the conclusions of the expert panel and misrepresented those conclusions in the draft minutes.

99. The Company apparently ignored Dr. Stein's comments on the minutes. In a January 3, 2008 email (first publicly disclosed on April 11, 2008 in connection with Congress's investigation), in response to having received a modified draft of the minutes after initially submitting his comments, Dr. Stein again insisted that the minutes be changed to reflect what truly happened at the meeting. In response to a statement in the revised minutes that "[t]he Panel was unanimous in their opinion that it was reasonable to elevate the common carotid to the primary endpoint," Dr. Stein commented:

> As stated in my 12-21-2007 comments, ***[t]his really overstates our recommendations. We did not vote on this.*** You asked each of us our opinions, the strength of which varied from complete comfort to a lukewarm feeling that it was 'reasonable.' The tone here

> implies that we strongly recommended this when in reality, we just advised you on what the scientifically valid approaches would be. ***It was the decision of the company to change the endpoint***.

(Emphasis added). As a result, Dr. Stein stated in his January 3, 2008 email that he could not "OK" or "approve" the Company's revised minutes. Nonetheless, the meeting summary was finalized in substantially the same form sometime thereafter in January 2008 (although misleadingly dated "November 16, 2007").

100. The Company's unusual and suspicious conduct with regard to the November 16, 2007 expert panel further supports a strong inference that the Company knew or recklessly disregarded the results of ENHANCE, sought further delay, and attempted to alter the study's pre-specified primary endpoint (a violation of the scientific method and widely-accepted scientific procedure for which it sought cover in the form of an expert panel that it manipulated).

G. Schering Attempted to Change the ENHANCE Primary Endpoint to One That Would Have Most Benefitted the Company

101. Soon after the expert panel meeting it had convened on November 16, 2007 – well after the data had been collected, and years after the study's protocol and data analysis plan had been finalized – Schering announced the highly unorthodox step of changing the primary endpoint of ENHANCE, purportedly based on the expert panel's conclusions. On November 19, 2007, Schering issued a press release announcing that, "an independent panel of clinical and biostatistics experts was convened on Friday, November 16, 2007 to offer advice about the prospective analysis of the ENHANCE trial." The release added that "[t]he independent panel recommended focusing the primary endpoint to the common carotid artery to expedite the reporting of the study findings." This press release announced that the primary endpoint was

being changed from the average of the multiple carotid artery measurements taken to the common carotid arteries only.

102. The November 19, 2007 press release stated that the recommendation to change the primary endpoint had been made by the panel of experts convened by Schering, and the release quoted Dr. Kastelein purportedly as stating his view – he later effectively recanted – that: "We view ***the experts panel's recommendation*** to narrow the primary endpoint to the common carotid artery as helpful." (Emphasis added). Moreover, the assertion that "[a] panel of outside scientists recommended the change" was repeated by Schering spokesman Lee Davies in the above-mentioned November 21, 2007 New York Times article. These statements, however, were false and misleading, because Schering, and not the expert panel, recommended the primary endpoint change.

103. Schering's announced change to the ENHANCE primary endpoint received immediate criticism from the scientific community. As The New York Times reported on November 21, 2007:

> [S]cientists generally assume that for a clinical trial to be valid, its goals must be defined before it begins and never changed afterward. Otherwise, the people conducting the trial could change their goals to conform to the data the trial has actually produced.
>
> ***"This sounds highly unusual to me,"*** said Dr. Bruce Psaty, a professor of medicine and epidemiology at the University of Washington [of the proposed ENHANCE primary endpoint change]. ***"You need to live with your primary endpoint."***

(Emphasis added).

104. Suspiciously, the modified endpoint that Schering officials proposed also was the endpoint most favorable to Schering under the final ENHANCE results as disclosed to the public

in March 2008. Although the ENHANCE results were not statistically significant, those results, as subsequently reported in the NEJM on March 30, 2008, showed that, of the several measurement sites that initially comprised the primary endpoint of ENHANCE (common carotid artery, carotid bulb, and internal carotid artery), the common carotid artery was the only site of the three that showed ***less of an increase*** in artery wall thickness for Vytorin treatment (corresponding to improved cardiovascular health) than for generic simvastatin treatment. By contrast, both the carotid bulb and internal carotid artery measurement sites showed ***greater increases*** in artery wall thickness for Vytorin treatment (corresponding to decreased cardiovascular health) in comparison to generic simvastatin.

105. The fact that the topic of changing the ENHANCE primary endpoint was raised by Schering officials during the November 16, 2007 meeting of experts, combined with how the modified endpoint that Schering officials proposed proved to be the endpoint most favorable to Schering under the final ENHANCE results as disclosed to the public in March 2008, further supports a strong inference that individuals at the Company in fact knew or recklessly disregarded the negative ENHANCE results before the November 16, 2007 expert meeting.

H. Defendants' Long Delay in the Release of the ENHANCE Results and Attempted Change of the Primary Endpoint Raised Suspicions from Doctors, the Media, and Congress

106. On November19, 2007, Forbes published an article discussing the lengthy delay in the release of the ENHANCE results after presentation of the results was again delayed (after they were expected to be presented at the American Heart Association meeting held in Orlando, Florida from November 3-7, 2007):

> Despite millions of prescriptions [for Zetia and Vytorin], no study has ever shown that these $3-a-day pills prevent heart attacks, strokes or deaths any better than just taking older drugs like Pfizer's Lipitor or Merck's off-patent Zocor, even though they're proven cholesterol fighters. That's why a two-year delay in a 720-person study [ENHANCE] aimed at clarifying the issue has cardiologists expressing skepticism and spinning conspiracy theories. If the news were good, the companies would rush it out, the thinking goes. Delay doesn't bode well.
>
> "It starts to raise suspicion," says Allen J. Taylor, head of cardiology at Walter Reed Army Medical Center. "The more time it takes, the more you start to naturally wonder what is wrong."
>
> * * *
>
> Right now, there's really no way to know what's going on with ENHANCE – at least, not until the data are made public.

Forbes reported that Walter Reed's Dr. Taylor was skeptical of the delay, stating that if Schering did not believe the results were positive, its incentive would be to delay as long as possible in the hope that better data might emerge from another study. The story also quoted Robert Califf of Duke University, Co-Chairman of the IMPROVE-IT trial (comparing Vytorin and simvastatin on their ability to prevent heart attacks), as stating: "We'd all agree that having this long a delay after a study's over is a bad thing."

107. As Forbes reported, at that time, Dr. Kastelein attempted to explain the delay in the release of the ENHANCE results by "narrat[ing] ***a long tale of woe***, including switching from roomfuls of VHS tapes to new digital imaging technology, training technicians and insuring the security of Internet connections." However, Dr. Kastelein also told Forbes that, with respect to the ENHANCE study, "***everything went smoothly*** . . . in terms of recruiting patients and taking artery measurements." (Emphasis added).

108. Forbes additionally reported that Schering and Merck had not listed the trial on the government website clinicaltrials.gov, where companies are required to register all clinical trials, until asked by Forbes.com about its absence. The Forbes article also noted that "[t]op clinical trial experts often now recommend that the outside researchers conducting a study, not the company, have control over the computerized database created to analyze study results [but in] this case, that database is held by Schering-Plough." According to the Second Amended Consolidated Complaint in the Merck Class Action, this fact is corroborated by Confidential Witness 5 ("Merck CW 5"), who was responsible for quality control of the ultrasound imaging in ENHANCE, among other things. According to Merck CW 5, Schering had control over the ENHANCE database from at least as early as 2006 and "S-P [Schering] had the code and the data in 2006 and performed the analysis."

109. The New York Times reported on November 21, 2007 that the delay in the release of the ENHANCE study results had led to "a growing chorus of complaints from cardiologists." Schering and Merck responded by "promising to publish a portion of the results next March – ***but not the entire set of data***." (Emphasis added). As The New York Times reported, "doctors say that decision is ***highly unusual*** and will do little to quell concerns about the trial, as well as broader questions about the effectiveness of the drugs." (Emphasis added). As the article stated:

> In June 2006, a Schering executive told investors that the Enhance data would be ready by year-end, although it might not be publicly presented until 2007. ***At the latest***, doctors had expected the results by the American College of Cardiology conference in March 2007. In an interview yesterday morning, Dr. Kastelein, the study's leader, said he had hoped to present the results of the trial at the March 2007 conference. But ***Schering and Merck controlled the raw data and raised questions about its accuracy***, resulting in long delays, he said. "***There was friction and tension***," he said.

(Emphasis added).

110. On December 11, 2007, Representative John D. Dingell, Chairman of the Committee on Energy and Commerce, and Representative Bart Stupak, Chairman of the House Oversight Subcommittee, sent a letter to Schering and Merck demanding information on the delayed release of the ENHANCE study results (the "First House Letter") and asking the companies to preserve documents concerning the study. The First House Letter stated the Representatives were "concerned with the delay in releasing the results of the study," "changing the trial's primary endpoint" and "the apparent manipulation of trial data."

111. Following the public disclosure of the First House Letter, without knowledge of the actual ENHANCE results, many practitioners remained confident that ENHANCE would provide favorable data demonstrating cardiovascular benefits of the drugs. As The New York Times reported: "Zetia has been proved to lower LDL, or bad, cholesterol by 15 to 20 percent. Every other medicine that lowers LDL also reduces heart attacks, and there is no reason to believe Zetia to be an exception, said Dr. Michael Crawford, the interim chief of cardiology at the University of California, San Francisco."

I. Defendants Backed Down from their Proposed Change in the ENHANCE Endpoint

112. On December 11, 2007, only twenty-two days after announcing that they were changing the primary endpoint of ENHANCE, and on the same date of the First House Letter, Schering and M/SP reversed course and announced that they would in fact not change the endpoint. This reversal was reported on a "Frequently Asked Questions" posting on Schering's website, where, in a response to the question, "Why didn't you change the primary endpoint?," Schering wrote:

> ***We view the expert panel's advice to focus the primary endpoint on the common carotid artery as helpful as the common carotid artery is viewed by many clinicians and experts of the IMT procedure as the most reliable, reproducible and clinically meaningful segment of the carotid artery and least subject to artifact and variability***. In consideration of this independent expert advice and the evolving medical science, Merck/Schering- Plough and the lead investigator have had further discussions about the trial, including input from other respected clinical trialists and scientists. The companies respect and appreciate the advice of the expert panel as well as the others whose advice and input we sought. As a result, we are planning to examine closely the data from the common carotid artery, and to present that data from the prespecified endpoints, in accordance with the study protocol and study analysis plan.

(Emphasis added). Schering again falsely attributed to the expert panel the decision to change the primary endpoint, although it was the decision of the Company to change the endpoint.

113. On December 17, 2007, The Wall Street Journal reported that Dr. Kastelein had "breathed a sigh of relief" when Schering and Merck advised him the previous week that they were reversing course and not changing the primary endpoint. The Wall Street Journal reported that Dr. Kastelein said "***he regrets not standing up to Merck & Co. and Schering-Plough Corp.*** when they first told him last month that ***they planned to alter the statistical analysis*** of their jointly sponsored trial." (Emphasis added). As the article reported:

> ***"It's never, ever right to change the primary endpoint of a study,"*** especially after all the data are in, [Dr. Kastelein] says. "It is statistically not good and it gives the wrong impression to the outside world." He says he initially went along with the plan but now regrets not firmly resisting it from the outset. ***He says the episode was the culmination of a long-running battle over the conduct of the trial and the companies' worries that some deficiencies in the data would jeopardize a good result. He says the concerns were unnecessary.***

(Emphasis added). Dr. Kastelein thus disclosed that it was the purported concerns of Schering and Merck – and not those of expert panel members – over alleged "deficiencies in the data" that

led to the delays in the release of the ENHANCE results and the proposed change in endpoint. Dr. Kastelein also concluded that Schering's purported concerns for delaying the results were, in truth, "unnecessary." However, the market was left to await the complete results of the ENHANCE study until months later.

114. The fact that Schering and Merck backed down so quickly from the proposed endpoint change further demonstrates that the proposed change itself lacked a sufficient basis. The reasons Schering and M/SP disclosed to the public for their proposal to change the endpoint were: (i) to "expedite the reporting of the study findings" in light of the alleged "time consuming" analysis of the data; and (ii) that measurement of the common carotid artery represented the "most reliable, reproducible and clinically meaningful segment of the carotid artery."

115. First, expediting reporting of the study's findings was not a true ground for Schering to propose changing the primary endpoint. In fact, the November 19, 2007 press release stated that, with a modification of the primary endpoint, Schering anticipated releasing the ENHANCE study data at the March 2008 ACC meeting. Even without modifying the endpoint, Schering was still able to meet that deadline, and, as discussed below, was able to release partial results of the ENHANCE study on January 14, 2008.

116. Second, the purported reliability of the common carotid artery measurement was not a valid basis for proposing it as the sole endpoint. In the March 30, 2008 NEJM article announcing the results of ENHANCE, there was no discussion that the common carotid artery measurements in the study represented what Schering had termed the "most reliable, reproducible and clinically meaningful segment of the carotid artery," and the article itself relied on the primary endpoint of the trial as initially announced – the average of measurements from the common carotid arteries,

carotid bulbs, and internal carotid arteries – to find that Vytorin provided no statistically-significant benefit over simvastatin.

117. Defendant Hassan also again downplayed the ENHANCE study at a conference hosted by Morgan Stanley on January 3, 2008, prior to release of the ENHANCE data, in which he stated that:

> [ENHANCE was] not a large trial, in a very, very special population with very, very high doses, the highest doses – these are not the mainstream doses. I don't know why this would have any impact on mainstream use. ***It's not the same population and it's not the same dosage***. And also the reading if this is not LDL which is the gold standard, this is some other approach which is hard to accomplish. So from everything I'm seeing this is one of many, many trials and it will advance the scientific knowledge but it's a small trial.

(Emphasis added).

V. Schering and M/SP Released Partial, and Then the Final ENHANCE Results in Early 2008

A. Schering and M/SP Released Partial, Negative Results of ENHANCE on January 14, 2008 that Partially Revealed Defendants' Fraudulent Concealment of the ENHANCE Results

118. On January 14, 2008, Schering and M/SP shocked the market by announcing selected results of the long-suppressed ENHANCE clinical trial. ENHANCE concluded that Vytorin is no better than simvastatin, a far less expensive generic drug, at reducing arterial wall thickness – a measurement of the progression of atherosclerosis. As the press release announcing the results concluded: "There was no statistically significant difference between treatment groups on the primary endpoint." In fact, the study showed that the arterial walls ***increased in thickness more*** in the patients taking Vytorin than in those taking simvastatin, although the results were not statistically significant. The change from baseline in the mean carotid IMT was +0.0111 mm for

the ezetimibe/simvastatin 10/80 mg Vytorin group versus +0.0058 mm for the simvastatin 80 mg group. The study's results thus raised serious questions about whether Zetia and Vytorin in fact benefited patients.

119. Dr. Steven Nissen, Chairman of the Department of Cardiovascular Medicine at the Cleveland Clinic, a widely-published researcher and senior consulting editor to the Journal of the American College of Cardiology, was surprised by the negative results, and particularly that the drugs did not show a benefit among patients with familial hypercholesterolemia. Dr. Nissen told Dow Jones that this population was the one "you'd most expect the drug to work in . . . if it doesn't work in this population it's not going to work in anyone" in slowing atherosclerosis. In an article appearing in the Journal of the American Medical Association ("JAMA") on February 27, 2008, the author reiterated that the ENHANCE patient population did not benefit from taking Vytorin, despite having been "specifically chosen because maximum benefit would be expected in such patients."

120. In a January 14, 2008 press release, Representatives Dingell and Stupak responded to the partial ENHANCE results by affirming that their investigation into the ENHANCE study would continue:

> "Today's announcement that the ENHANCE study failed to find any positive benefit from the addition of Zetia to a common, inexpensive, generic therapy ***raises concerns that attempts were made to mask the minimal value of this new drug. Additionally, Merck and Schering-Plough's delay in releasing study results, as well as their attempt to manipulate the data is, quite frankly, suspicious," said Dingell. . . .***
>
> "In light of today's results, which were released nearly two years after the ENHANCE trial ended, ***it is easy to conclude that Merck and Schering-Plough intentionally sought to delay the release of this data***," said Stupak.

(Emphasis added).

121. On January 14, 2008, Cowen & Company reduced its estimate of the drugs' annual sales by $600 million by 2010. Merrill Lynch also immediately reduced its rating on Schering's stock from "Buy" to "Neutral":

> ***We do not see SGP stock as a Buy when the momentum of the key financial driver is uncertain.*** Although ENHANCE results were not statistically significant, Vytorin use resulted in a doubling of plaque progression relative to Zocor alone, and the incidence of cardiovascular events was marginally numerically higher for Vytorin than Zocor alone in three of four measures. ***Although Vytorin lowered LDL 58% vs. Zocor's 41% reduction, the benefit to patient health is unclear. Recall that the Vytorin/Zetia JV represents over two-thirds of SGP's profits.***
>
> We expect uncertainty about Vytorin and Zetia to weigh on Schering Plough's stock. Cardiovascular thought leaders are likely to question the benefits of Vytorin and Zetia, and some may even raise questions about whether Zetia counter-acts the pleiotropic ("many") effects of statins – which refers to the clinical benefits of statins beyond their effect on lowering cholesterol levels. We thus think market share could shift some toward statins (i.e. Crestor, Lipitor, Zocor).

(Emphasis added).

122. As The New York Times reported on January 15, 2008: "[T]he drug companies blamed the complexity of the data for the delay. Now, barely a month after news articles noted the delay and Congress pressured the companies to disclose the study's findings, the results are out." As Dr. Harlan Krumholz, a cardiologist at Yale University, stated in The New York Times, drug companies have a responsibility to release all their trial findings, positive or negative, as quickly as possible – even if the results might hurt sales: ***"People may have been on this drug without the ability to know that there was additional data that may have thrown into question its effectiveness. . . . That's extremely unfortunate, and that's an understatement."*** (Emphasis

added). The Cleveland Clinic's Dr. Steven Nissen stated in the January 15 New York Times article that, ***"This is as bad a result for the drug as anybody could have feared."*** (Emphasis added). In an interview that same day with WebMD, Dr. Nissen called the results ***"a stunning reversal for ZETIA and VYTORIN."*** (Emphasis added).

123. As The New York Times further reported on January 16, 2008:

> There have long been suspicions, but it was still very disturbing to learn this week that a heavily promoted cholesterol-lowering drug had flunked a clinical trial of its effectiveness in reducing fatty deposits in arteries. The two companies that reap billions from the drug had been ***cynically sitting on the results for more than a year***.

(Emphasis added).

124. In a January 17, 2008 Newsweek article, in response to the question, "Do you think that Schering-Plough and Merck intentionally sought to delay the release of this data?," Representative Stupak stated: "Do I think they knew about it and attempted to put lipstick on the pig, so to speak? ***Yes***. ***They knew about it***. This was their blockbuster drug. Take away $5 billion or more from these companies, and man . . . These allegations are very serious though. We've been on this since October, and we have enough information to go for a hearing now." (Emphasis added).

125. Partial revelation of the true facts caused an immediate decline in the Company's common and preferred stock prices on January 14, 2008, as discussed further, *infra*. In response to further growing concerns discussed in news articles published on January 15, the Company's common stock price declined further on January 15, 2008, as discussed further, *infra*.

126. Following the partial release of the ENHANCE results, Hassan pointed to Schering's fall 2007 acquisition of Organon as one positive aspect of Schering's business, which, in fact, would have been severely jeopardized by the Company's release of the ENHANCE results prior to August 2007. As The Wall Street Journal reported on January 17, 2008: "The mishandling of what should have been a relatively routine study of two of Schering-Plough Corp.'s most profitable drugs ***threatens to deal a serious setback to the painstaking turnaround implemented by Chief Executive Fred Hassan***. . . . Meanwhile, Mr. Hassan pointed to Schering's growth sources beyond its cholesterol franchise, including its pipeline and portfolio of current products. Both expanded with last year's . . . acquisition of Organon Biosciences, NV." (Emphasis added.)

127. On January 17, 2008, The Wall Street Journal also reported on widely-circulated reports that raised questions about the suspicious timing of Defendant Cox's April and May 2007 sales of $28 million worth of Schering stock, and that Cox's sales were also the focus of Congressional scrutiny.

B. Congress and State Attorneys General Increased their Scrutiny of Schering's Conduct with Respect to ENHANCE

128. On January 16, 2008, Representatives Dingell and Stupak sent a follow-up letter to Merck and Schering requesting documents concerning ENHANCE and the marketing of Vytorin (the "Second House Letter"). The Second House Letter noted that although ENHANCE ended in April 2006 and both Schering and Merck indicated that the results had not been un-blinded and were not ready for presentation as of December 2007, within just one month the study results were available in a press release. Further, DTC advertisements continued for nearly two years after the study was completed and the results were not made public. The letter additionally noted

that Dr. Kastelein had been excluded from the meeting at which a panel of outside experts purportedly had decided to change the study's endpoint, and the letter requested documents, including communications between Dr. Kastelein and the panel.

129. On January 22, 2008, Representatives Dingell and Stupak sent a third letter (the "Third House Letter") requesting additional documents from Schering and Merck, including those related to any outside advisory committees and boards that may have reviewed ENHANCE, as well as a request that Schering and Merck identify when senior officers learned of the study results, given that Schering officer Defendant Cox sold significant numbers of Schering shares in the time between the end of ENHANCE and the release of the partial results in January 2008.

130. On January 22, 2008, Schering and Merck announced that they had suspended television advertising for Vytorin. Television advertisements had also been suspended for Zetia.

131. On January 24, 2008, a fourth letter from Representatives Dingell and Stupak requested information about Merck and Schering's financial ties to the American College of Cardiology ("ACC") and the American Heart Association ("AHA"), out of concern that such "strong financial ties" might impact the ACC and AHA's review of ENHANCE. On that date, Senator Charles Grassley, ranking member of the Senate Finance Committee, also sent a letter (the "First Senate Letter") jointly addressed to Schering CEO Defendant Hassan and Merck CEO Richard Clark, expressing concern that the companies "had the study results since April 2006, more than 20 months ago" and that "there is no apparent gain in health benefits from using Vytorin over the much cheaper generic statin, simvastatin." Senator Grassley further cited Defendant Cox's sales of 900,000 shares of Schering stock for gross proceeds of $28 million "during the time when executives of the company were delaying the release of the ENHANCE results." Senator

Grassley made several document requests and sought answers to several questions and also wrote to SEC Commissioner Christopher Cox, ACC President James Dove, and AHA CEO M. Cass Wheeler to express his concerns about the long-delayed release of ENHANCE.

132. On January 25, 2008, the FDA announced it would review ENHANCE to determine if any regulatory action should be taken against Schering and Merck.

133. On January 25, 2008, Forbes printed an article discussing the release of the partial ENHANCE results. The story reported that Dr. Harlan Krumholz of Yale University was concerned the delays were caused by commercial – not scientific – concerns. "By the summer of 2005, their marketing division is so successful that it already is a blockbuster drug. There was only downside [to analyzing the results]." Dr. Allen Taylor of Walter Reed found that spending so long purportedly trying to clean up the data was not appropriate: "It's not liking the answer and hoping that if you do it again you'll get a better answer . . . The fact they never found a good solution validates the point: The data are the data."

134. Forbes also published comments from doctors on January 25, 2008 concerning the lack of a data safety monitoring board ("DSMB") for the ENHANCE study. Steven Joffe, a bioethicist and researcher at the Dana Farber Cancer Center stated that the lack of a DSMB was "sub-optimal." In his words: "It's hard to see who is helping to shape these decisions who has a strong level of independence from the company. Who has seen the data who can take public accountability?"

135. On January 26, 2008, The Wall Street Journal reported on continued suspicions in the medical community concerning the companies' delayed release of the ENHANCE results. In the

article, Yale's Dr. Krumholz stated: ***"It's in their great interest to delay this study if there is any possibility that it doesn't come out positive."*** (Emphasis added).

136. Also on January 26, 2008, New York Attorney General Andrew Cuomo issued subpoenas to Schering and Merck concerning the ENHANCE results, and on January 29, 2008, Connecticut Attorney General Richard Blumenthal announced an investigation of Schering related to ENHANCE.

137. On February 11, 2008, letters from Congressmen Dingell and Stupak and the House Energy and Commerce Committee demanded additional documents from the chief executives of both Schering and Merck because, *inter alia*, in light of the ENHANCE results, the above-described messages posted to cafepharma.com demonstrated apparent knowledge of ENHANCE results as early as March 13, 2007, nine months before the data were publicly released, and the companies' prior responses revealed that Schering biostatisticians began "conducting routine data quality reviews of the initial blinded ENHANCE data" in the "[s]ummer through the end of 2005" ("Fifth Set of House Letters"). Also on February 11, 2008, Senator Grassley wrote a follow-up letter to Defendant Hassan containing five questions (excluding subparts) seeking additional information pertaining to the ENHANCE data, its transfer between Schering entities, the personnel involved in analyzing the data, emails discussing the results of ENHANCE, and emails between Dr. Kastelein and Schering employees ("Second Senate Letter").

C. Prior to the Release of the Full ENHANCE Data, the Market Remained Optimistic that the Full ENHANCE Results Would Show Some Cardiovascular Benefits of Zetia and Vytorin

138. The January 14, 2008 release of the partial ENHANCE results did not disclose all of the pertinent data from the trial, and doctors and the market remained optimistic that the Company

and M/SP's eventual release of the full results in March 2008 would provide some information demonstrating some cardiovascular benefits of Zetia and Vytorin. For instance, a March 20, 2008 Leerink Swann research report stated: "[C]ardiology consultants . . . expect the presentation of the ENHANCE results on Sunday March 30th, to 'clear the air' and confusion around the study . . . . [T]hey believe the discussion will clear up any confusion and highlight the positive impact that Zetia had on LDL cholesterol & C-reactive protein in ENHANCE." A March 26, 2008 Lehman Brothers research report added: "We expect ENHANCE to be the single most attended session [at the ACC conference] as investors look to get an edge on the full data set for ENHANCE."

139. Just before the full ENHANCE results were released, Dow Jones reported on Friday, March 28, 2008:

> While the top-line study results are already out, doctors are looking for additional information from the study, which will be reviewed by an expert panel of cardiologists [at the ACC conference].
>
> Prescription volume for both Vytorin and Zetia has declined since January. ***But the full data could paint a more complicated picture, and one that is potentially favorable to the drugs***.
>
> Also, the study is expected to provide a breakdown of the various measurements of carotid artery thickness, including a site on the artery called the "common carotid." The top-line data were an average of thickness at three different sites on the artery. And doctors expect to learn more about the data-quality problems that appeared to arise during the course of the trial, which both Merck and Schering-Plough have said partly accounted for the long delay in releasing trial results.

(Emphasis added).

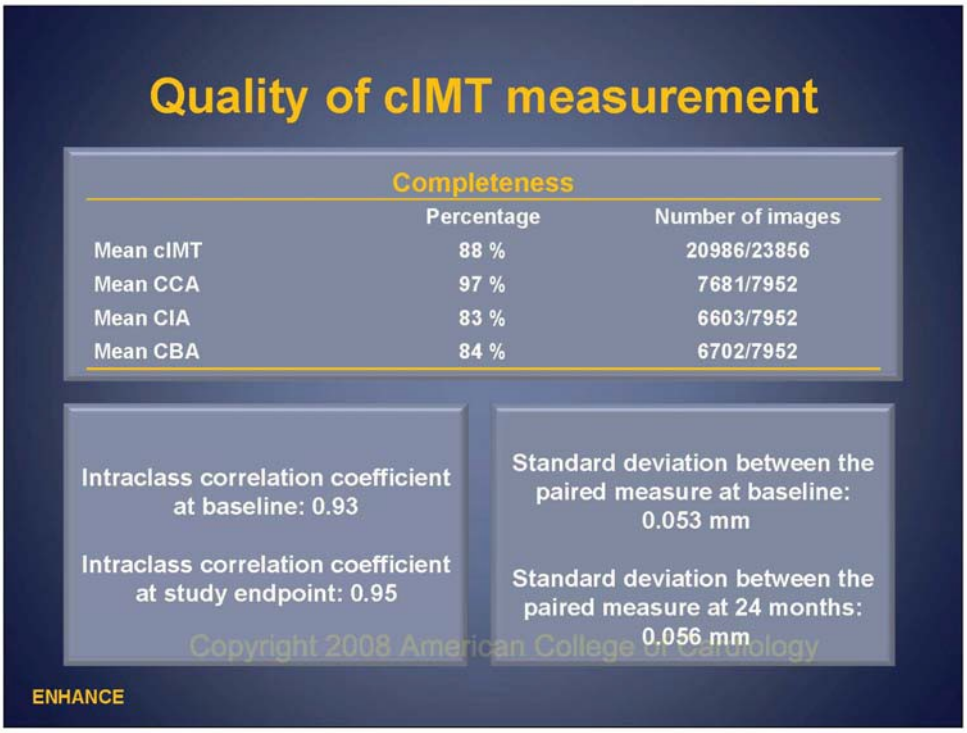
D. Schering and M/SP Released the Full ENHANCE Data on March 30, 2008, Which, According to the Study's Principal Investigator, Showed "Zilch" Cardiovascular Benefits

140. On March 30, 2008, ten weeks after the initial release of certain ENHANCE data, at a conference held by the ACC in Chicago (the "Chicago ACC Conference"), Dr. Kastelein presented the final results of ENHANCE in their entirety.

141. Dr. Kastelein's presentation affirmed the conclusion that Vytorin was no better at reducing the progression of atherosclerosis than simvastatin alone. According to Dr. Kastelein, Zetia and Vytorin had ***"no result – zilch. . . . [i]n no subgroup, in no segment, was there any added benefit"*** in terms of reducing plaque buildup in arteries. Dr. Kastelein's presentation also pointedly addressed the issue of the quality of the ENHANCE data. While displaying a slide captioned "Quality of cIMT measurement" (reproduced below) Kastelein put to rest the notion that the technical execution of ENHANCE was a problem:

> What about the technique? The quality measures in our trial are listed on this slide, and you can see that there is an 88% completeness of data for the primary endpoint. Intraclass correlation coefficient – very high – .93. And standard deviation actually .053, which is more than three times as good as we assumed in our original power calculation. ***And therefore, it is highly unlikely, if possible at all, that you can blame the technique for the results of this study***.

(Emphasis added). The slide to which Dr. Kastelein referred is as follows:



142. Immediately following the presentation, a panel of cardiologists appointed by the ACC to review the study results presented its conclusions to the conference. Dr. Krumholz, the Yale cardiologist, spoke on behalf of the panel: "You've just seen a negative trial that should change practice, especially the way we in this country have prescribed [Zetia and Vytorin]." Dr. Krumholz added that "[i]t seems to be a very strong study," and further advised cardiologists that "[o]ur strongest recommendation is that people need to go back to statins." In Dr. Krumholz's words, ENHANCE raised the possibility that ezetimibe is just an ***"expensive placebo."***

143. At a press conference following the presentation, the panelists stated that they supported Dr. Krumholz's statements. For instance, panel member Dr. Rick Nishimura of the Mayo Clinic said the outcome of ENHANCE ***"reminds us to look at the trial endpoint and how (drugs) affect patients and not to just look at the numbers."*** On March 31, 2008, The New York Times

reported on the panelists' findings and quoted Dr. Nissen of the Cleveland Clinic as stating: "I advise my colleagues essentially to use this drug ***only as a last resort***." (Emphasis added). In connection with the Chicago ACC Conference, cardiologist and President-elect of the ACC, W. Douglas Weaver, stated that: "What this tells us is that we have had far too many patients on these drugs than the science supports."

144. Also on March 31, 2008, the NEJM published the ENHANCE results in an article written by Dr. Kastelein and other doctors entitled "Simvastatin with or without Ezetimibe [Zetia] in Familial Hypercholesterolemia." The NEJM article concluded: "In patients with familial hypercholesterolemia, combined therapy with ezetimibe and simvastatin [*i.e.*, Vytorin] ***did not result in a significant difference*** in changes in intima-media thickness, as compared with simvastatin alone." (Emphasis added).

145. Another article published in the NEJM that day discussing DTC advertising for Vytorin summarized the findings of the ENHANCE study in the following terms:

> The ENHANCE study by Kastelein et al. ***did not provide evidence that ezetimibe [Zetia], as an adjunct to simvastatin, reduced the progression of atherosclerosis, as compared to simvastatin alone,*** even though ezetimibe was associated with the expected additional reduction in LDL cholesterol levels.

(Emphasis added).

146. The chart below summarizes the data reported by the NEJM concerning the change in thickness (over two years) of patients' arterial walls as an average of the six segments (common carotid artery, carotid bulb, and internal carotid artery in each of the left and right arteries), and each site individually, for simvastatin alone ("Simvastatin Monotherapy") versus Vytorin ("Simvastatin plus Ezetimibe"):

Average intima-media thickness of carotid artery (mm)	Simvastatin Monotherapy	Simvastatin plus Ezetimibe
Average of 6 segments	0.0058 +/-0.0037	0.0111 +/-0.0038
Common carotid artery	0.0024 +/-0.0043	0.0019 +/-0.0044
Carotid bulb	0.0062 +/-0.0069	0.0144 +/-0.0070
Internal carotid artery	-0.0007 +/-0.0064	0.0099 +/-0.0065

With the exception of the common carotid artery IMT measurement, these results show greater progression of the atherosclerotic process for patients in the Vytorin cohort than in the simvastatin cohort, although at levels that were not statistically significant. The slightly increased IMT recorded for simvastatin over Vytorin for the common carotid artery (amounting to a mere 0.0005 mm) was not significant either. None of these results demonstrated any cardiovascular benefit of treatment with Vytorin versus treatment with simvastatin alone. In an editorial addressing Dr. Kastelein's article published in the same issue of the NEJM, Drs. B. Greg Brown and Allen J. Taylor wrote: "[A]lthough a reduction in intima-media thickness does not guarantee a reduction in the rate of events, it seems unlikely that a reduction in events can be expected without a reduction in the progression of intima-media thickness." They advised clinicians to use Schering's Zetia only after failing to reach desirable cholesterol targets with statins and other drugs that show clinical benefits when added to statins.

E. The Revelation of the Full ENHANCE Results Had a Profound Negative Impact on Schering's Securities' Prices and Led to Sharp Drops in Prescription Levels and Layoffs at Schering

147. On Monday, March 31, 2008, the first business day after the Chicago ACC Conference and publication of the articles in the NEJM, Schering's common and preferred stock prices suffered another drop caused by the disclosure of the ENHANCE results, as discussed further, *infra*, causing further damage to shareholders.

148. The Associated Press reported on March 31, 2008 that, despite Schering's disclosures regarding the purported poor quality of the data, "[Dr.] Kastelein said the data were far more consistent than anticipated and ample to show that the drug simply did not work." Doctors were in fact surprised that the full results of the study were so negative. As cardiologist Dr. Roger Blumenthal of the Johns Hopkins University stated in the article: "A lot of us thought that there would be some glimmer of benefit." However, there was none.

149. On March 31, 2008, The Wall Street Journal quoted Dr. Kastelein as stating: "[W]hatever way you look at the data, the addition of [Zetia] didn't make a difference." Dr. Kastelein stated the additional efforts taken by Schering and Merck "to refine the data were of no value," and indicated that ***"he would have been ready to present the findings as long as a year ago [March 2007] if the company had released the data to him."***

150. Wall Street analysts also reacted negatively to the ENHANCE news:

- In a report entitled "ACC Panel – 'Zetia an Expensive Placebo,'" Lehman Brothers analyst C. Anthony Butler downgraded Lehman's rating of Schering to "equal weight" from "overweight" and reduced the stock's price target from $35 to $20. Butler stated that "We view yesterday's commentary as negative and given the prominence of the ACC venue conclude that ***the fundamental investment thesis for SGP has changed.*** We take this catalyst as an opportunity to downgrade our rating on SGP to a 2-Equal- weight from a 1-Overweight. We cite the following rationale for the downgrade: 1. Significantly greater than expected total prescription decline[;] 2. Increased uncertainty of managed care formulary position[; and] 3. SGP's reliance on the JV equity income generated from Zetia and Vytorin. We note that the JV contributes just over 60% of SGP's 2009 EPS estimates in our model." Butler also changed his price target for Merck from $65 to $58.

- Goldman Sachs analyst James Kelly downgraded Schering to "Neutral" and lowered his price target from $28 per share to $23 per share. Kelly stated that, "The Enhance data were presented this weekend and were not surprising. ***The big surprise was the professional commentary, which spoke to limiting the use of the drug (until after cholesterol-lowering medicines have failed) unless it is proved in an outcomes trial (expected to be completed in 2012). Given the***

uncertainty around the franchise, we are downgrading Schering-Plough stock to 'neutral'."

- Catherine Arnold of Credit Suisse called the panelists' discussion ***"surprisingly negative"*** and lowered her estimate for VYTORIN market share.

- Cowen and Company's Steve Scala downgraded Schering to neutral, noting that "a thorough review of the ENHANCE data . . . clearly demonstrates that ***the addition of Zetia to simvastatin failed to lead to a benefit.***"

- Seamus Fernandez of Leerink Swann, an investment bank specializing in healthcare, stated: "The expected panel discussion ended up being more of a consensus statement that concluded ***1) ENHANCE was a well-conducted high-quality imaging study; 2) there is no evidence from ENHANCE that the combination performs better than the same dose of statin alone; 3) LDL-lowering is not an infallible surrogate; and 4) ZETIA/VYTORIN should be reserved for last-line therapy after trying multiple statins and other 'evidence-based' therapies (bile acid resins, fibrates and niacin). Since the panel recommended that ZETIA be considered as a 3rd- or even 4th-line therapy, we believe a recovery in prescriptions in unlikely in 2008 and there could be additional negative impact on U.S. prescriptions post-ACC.***"

(Emphasis added).

151. Following disclosure of the ENHANCE results, prescriptions of Zetia and Vytorin plummeted. As the Company disclosed in a Form 8-K dated July 17, 2008, U.S. Total Prescription Volume for Zetia and Vytorin has steadily decreased since January and March 2008. The chart below lists the prescription figures disclosed by the Company (in thousands):

	January 2008	**February 2008**	**March 2008**	**April 2008**	**May 2008**	**June 2008**	**% Change (Jan. vs. June)**
Vytorin	1,839	1,597	1,610	1,420	1,404	1,330	-27.68%
Zetia	1,366	1,176	1,193	1,072	1,060	1,022	-25.18%
Total	3,205	2,773	2,803	2,492	2,464	2,352	-26.61%

152. Following the release of the complete ENHANCE results, the three major credit rating agencies all downgraded their ratings of Schering's debt. Fitch Ratings downgraded $11.98 billion in outstanding Schering debt to "Rating Watch Negative," noting in its press release that

the downgrade "reflects Fitch's concern that Schering-Plough will be unable to reduce leverage … given potential sales erosion of the cholesterol-lowering medicines, Vytorin and Zetia." Fitch noted that "[s]ales decline experienced since the release of clinical data from the ENHANCE study in January moderated late in the first quarter of 2008, but may trend downward depending on the application by cardiologists and primary care physicians on a recommendation by a panel of physicians at the recent American College of Cardiology (ACC) meeting." Similarly, Moody's reduced Schering's outlook to "negative" and Standard & Poor's placed the long-term rating for Schering, including the Company's "A-" corporate rating, on "CreditWatch Negative."

153. Further demonstrating the material negative impact that the ENHANCE results have had on the Company, on April 2, 2008, as a result of the significant decrease in Zetia and Vytorin sales resulting from release of the ENHANCE results, Schering announced that it was launching an effort to reduce costs called the "Productivity Transformation Program," which included significant layoffs, to generate "a total of $1.5 billion in targeted annual savings and synergies." The layoffs totaled approximately 5,500 employees, which was 10% of Schering's 55,000-member work force. In Defendant Hassan's words: "We are taking the tough actions that are needed to respond to a tough situation."

154. On April 11, 2008, Congressmen Dingell and Stupak sent a letter to Defendant Hassan at Schering, and Merck's CEO Richard Clark, asking them 14 questions in connection with their ongoing investigation of the delayed release of the ENHANCE results. According to the Congressmen, their investigation was "by no means concluded." The letter stated that the nearly two-year delay in the release of the results was "unusual for a clinical trial" and that they

"continue[d] to have serious concerns related to the conduct and reporting of this study." Attached to the letter were seventy pages of documents the companies had produced to the Committee, which were not previously publicly available, including: (i) the Bots Report; (ii) correspondence between Dr. James Stein and Schering's Dr. John Strony concerning the proposed "minutes" of the November 16, 2007 outside consultants' meeting; and (iii) certain materials presented at the November 16 meeting.

155. Also on March 31, 2008, Senator Grassley wrote a follow-up letter to Defendant Hassan containing three questions (excluding subparts) seeking additional information pertaining to ENHANCE ("Third Senate Letter").

VI. The Facts Give Rise to a Strong Inference that Defendants Acted with Scienter

156. The facts set forth above, viewed collectively, give rise to a strong inference that Defendants acted knowingly, or at least recklessly, when they concealed from the market the material negative results of ENHANCE, which, when they were disclosed, had a significant, negative impact on Schering and M/SP's sales of Zetia and Vytorin, the price of Schering securities, and Schering's business as a whole.

157. Based on interviews with former Schering employees conducted by counsel for the lead plaintiffs in the Schering-Plough Class Action, Defendants Hassan and Cox were closely involved with ENHANCE and regularly briefed on its details. As discussed above, CW 1 interacted with Schering's Brand Team on a daily basis regarding Zetia and Vytorin, and updates regarding ENHANCE were shared in quarterly Brand Review Meetings that CW 1 attended, which were conducted by Defendant Cox. According to CW 1, there was a quality control assessment of ENHANCE data done in late 2005 to early 2006, and by the summer of 2006, CW

1's team ***"knew that they were not going to get any good news from"*** ENHANCE. This fact was confirmed by the March 24, 2008 Wall Street Journal Article in which representatives of Schering, M/S-P, and Merck admitted that "Dr. Kastelein's team began sending complete measurements from the first group of patients" in "late 2005" following which statisticians "began routine checks to make sure the data were in order."

158. CW 1's statements are corroborated by Confidential Witness 3 ("CW 3"). According to the Consolidated Class Action Complaint in the Schering-Plough Class Action, CW 3 is a doctor who worked at Schering from before 2002 to early 2007. According to CW 3, throughout the Relevant Period, Defendant Cox attended a monthly meeting with the cholesterol franchise Brand Team and the individuals in charge of ENHANCE, Drs. Veltri and Strony. CW 3 was personally involved in the preparation of certain materials for these meetings. According to CW 3, the Company's other senior executives, including Defendant Hassan, also attended certain of these meetings. According to CW 3, ENHANCE, its progress, and results, were regularly discussed by Drs. Veltri and Strony with Defendant Cox and the other senior executives in attendance. At the meetings, discussions and detailed PowerPoint presentations updated the participants on developments with Vytorin and Zetia, involving not only the marketing and commercial aspects of the drugs, but also the status of ongoing research. As CW 3 has stated: "Nobody keeps this kind of stuff from management when it is going to have a huge impact on the product."

159. The following facts, among the others set forth above, further give rise to a strong inference of scienter by Defendants:

- Zetia and Vytorin Were Schering's Core Business. As discussed above, Zetia and Vytorin accounted for between 60-70% of Schering's earnings, and Schering acknowledged in its 2006 and 2007 Forms 10-K, among other publicly-filed documents, that its "ability to generate profits and operating cash flow depend[ed] ***largely upon the continued profitability of . . . VYTORIN and ZETIA***." Defendants' misrepresentations and omissions concerning the success of Zetia and Vytorin thus involved the Company's core business, and the individual Defendants, as senior executives of the Company, would have closely followed any developments that could impact sales of those drugs, such as ENHANCE. In fact, the individual Defendants Hassan and Cox discussed Zetia and Vytorin in the quarterly earnings calls with investors held by the Company during the Relevant Period. The importance of Zetia and Vytorin to the Company thus further raises a strong inference that Schering's senior executives paid close attention to and were knowledgeable regarding the results of ENHANCE.

- Schering Doctors and Statisticians Were Closely Involved in ENHANCE. Schering doctors Strony, Veltri, and Bransford were primarily responsible for ENHANCE and participated in numerous key actions and communications regarding it. Drs. Strony and Bransford commissioned the Bots Report on behalf of Schering; Drs. Strony and Veltri were the recipients of the July 2007 emails from Dr. Kastelein expressing Dr. Kastelein's surprise and disagreement over the continued delayed release of the ENHANCE results; numerous Schering individuals attended the November 2007 expert panel meeting to discuss the change in the study's primary endpoint and authored materials prepared for the meeting, including Drs. Veltri and Strony and statistician Bo Yang; and Dr. Strony received Dr. James Stein's comments on the proposed draft "minutes" of the November 2007 expert panel meeting where Dr. Stein stated, *inter alia*, that "it was the decision of the company to change the primary endpoint."

- Schering Had Access to, and Control Over, the ENHANCE Data. Typically, entities called clinical review organizations, and not the company sponsoring the study, have control over the computerized database created to analyze study results. However, this was not the case with respect to ENHANCE, since the data was in Schering's control. Schering's access to the data provided the Company with the ability to monitor the results on an ongoing basis and delay their release. Indeed, Dr. Kastelein stated after the Relevant Period that if he had been in control of the study data, he could have released its results by March 2007. Schering's access to the database (and thus the ENHANCE results) further raises a strong inference that Defendants acted with scienter.

- Schering Was Aware of the January 2007 Bots Report. The Bots Report, commissioned by Schering by Drs. Strony and Bransford, concluded that the quality of the ENHANCE data was "fine." Defendants therefore had no scientifically-valid reason to delay their release; this further raises a strong inference of scienter.

- Public Posts Appeared on www.cafepharma.com as early as March 2007 and Revealed Knowledge of the ENHANCE Study Results. The anonymous postings revealing the ENHANCE results gained significance upon being confirmed by the Company's own early 2008 release of those results.

- Schering Selectively Provided the November 2007 Panel of Consultants with Negative Data and Wrongly Attributed to the Panel the Proposal to Change the Study's Primary Endpoint. Schering convened the expert panel to deal with purported problems with the ENHANCE data. Schering then provided the panel with information painting an overly negative picture of the data, including that the "[e]xisting data is not statistically analyzable," and that "[t]here is [a] tremendous risk analyzing this data." Yet, Schering and M/SP (under pressure from Congress) released preliminary results of ENHANCE (based on this same data) only two months later. Schering and M/SP also announced their unprecedented plans to change the primary endpoint of the study based on the purported recommendation of the panel – a breach of scientific protocol that was not in fact the panel's recommendation – only to reverse course on the change shortly thereafter. Schering and M/SP also fabricated "minutes" of the panel meeting in order to support their (false) claim that the panel recommended changing the primary endpoint.

VII. The Individual Defendants Had the Motive and Opportunity to Withhold the ENHANCE Results

160. In addition to the foregoing facts, all of which support a strong inference of scienter on the part of Defendants, the individual Defendants Hassan and Cox also had the motive and opportunity to withhold the ENHANCE results. Hassan and Cox both acted with scienter in that, as set forth herein, both knew or recklessly disregarded that Schering's public statements about Zetia and Vytorin issued prior to and throughout the Relevant Period were materially false and misleading. These Defendants were the senior management of the Company, and thus at all times were the individuals with principal responsibility for ensuring that the Company's statements were accurate and truthful.

A. Defendant Hassan Had the Motive and Opportunity to Withhold the ENHANCE Results

161. At all times relevant to this Complaint, Defendant Hassan served as CEO and Chairman of Schering's Board of Directors. According to the Company's public filings and press releases,

Schering's overall corporate strategy was the responsibility of Defendant Hassan. Indeed, as the Company stated in its Proxy Statements to shareholders, Hassan has been principally responsible for Schering's entire management team since 2003. Schering recruited Hassan in 2003 after the Company replaced its top management team when faced with significant challenges (as discussed above), including numerous government investigations and fines. Soon after being hired, Hassan recruited a new executive management team, including all of the other key executives. Schering's corporate strategy during the Relevant Period was directed by Hassan, and that strategy included the material delay and omission of the ENHANCE results from Schering's public statements to misrepresent the financial strength of the Company.

162. As of the filing of the Company's Proxy Statement on March 22, 2006, Defendant Hassan beneficially owned 2,503,501 shares of Schering common stock (which included shares which could be acquired within 60 days of February 27, 2006 through the exercise of employee stock options). And, as of the Company's Proxy Statement filed with the SEC on April 20, 2007, Defendant Hassan beneficially owned 3,677,466 shares of Schering common stock (which included shares which could be acquired through the exercise of employee stock options that would vest within 60 days of March 28, 2007). Mr. Hassan therefore had a direct and significant personal pecuniary interest in the success of Schering's common stock, which provided a motive for him to withhold the ENHANCE results.

163. On January 18, 2008, Schering announced Hassan's intention to make an open market purchase of $2 million of Schering common stock with personal funds to "reflect[] [his] long-term confidence in the company, its products (including Zetia and Vytorin), and [Schering's] late-stage pipeline." In the press release, Hassan commented on Schering's recent drop in share

price caused by the partial release of the ENHANCE data. He stated that, "the media interpretations of the top-line ENHANCE trial results, and the resulting stock price reaction, have been deeply troubling." However, the January 18, 2008 press release disclosed that Hassan in fact intended to delay his $2 million purchase of Schering stock until after the ACC meeting. Thus, Hassan sought to obtain the benefits of a favorable market reaction in response to his January 18, 2008 press release, without actually purchasing shares until after March 30, 2008.

164. On April 24, 2008, Hassan purchased 110,000 shares of Schering stock worth $2,008,773, at prices ranging from $18.21 to $18.29. Those prices were more than $8.50 lower than Schering's $26.85 closing price on January 18, 2008, and among the lowest prices of Schering stock in the time period from July 2006 through March 2008. (From July 24, 2006 through March 30, 2008, the price of Schering stock never fell below $18.57, except on January 25, 2008, when the share price hit $17.45.)

B. Defendant Cox Had a Motive and Opportunity to Withhold the ENHANCE Results

165. At all times relevant to this Complaint, Defendant Cox served as Executive Vice President and President, Global Pharmaceuticals of the Company, and presided over the cholesterol franchise. Cox had direct reporting responsibility for the sales performance of Zetia and Vytorin, and during all of the quarterly earnings report conference calls during the Relevant Period, Cox discussed the sales figures for Zetia and Vytorin. According to Schering's website, Cox was "responsible for leading the transformation of the Global Pharmaceutical Business into a profitable, high-performing organization." Schering's strategy to make the Global Pharmaceutical Business profitable during the Relevant Period was based principally on sales of

Zetia and Vytorin, as well as the material delay and omission of the ENHANCE results to misrepresent the financial strength of the Company.

166. As of the filing of the Company's Proxy Statement filed with the SEC on March 22, 2006, Cox beneficially owned 983,334 shares of Schering common stock (which included shares which could be acquired within 60 days of February 27, 2006 through the exercise of employee stock options). And, as of the Company's Proxy Statement filed with the SEC on April 20, 2007, Defendant Cox beneficially owned 1,382,871 shares of Schering common stock (which included shares which could be acquired through the exercise of employee stock options that would vest within 60 days of March 28, 2007). Cox therefore had a direct and significant personal pecuniary interest in the success of Schering's common stock.

1. Insider Stock Sales by Defendant Cox During the Relevant Period Were Highly Unusual in Scope and Timing, and Raise a Strong Inference She Had a Motive and Opportunity to Withhold the ENHANCE Results

167. In April 2007, just one month after the ENHANCE CaféPharma posts began to appear, Cox exercised Schering stock options and sold common stock worth over $28 million in the open market at a time when the price of Schering stock had been inflated by the Company's failure to disclose the ENHANCE results. Cox's sales were highly unusual in scope and timing and represented a concrete and personal benefit to her which resulted from the non-disclosure of the ENHANCE results at a time when facts raise a strong inference that she knew or recklessly disregarded those negative results.

168. In May 2003, when Cox joined Schering, she was granted 450,000 stock options with a strike price of $18.50 per share as part of her employment contract. These options vested in one-

third increments in 2004, 2005, and 2006. In February 2004, Cox received an additional 450,000 stock options with a strike price of $18.20 per share. These, too, vested in one-third increments in 2005, 2006, and 2007. Stock options provide the grantee with the right to purchase the company's stock at the strike price and then sell those shares in the open market at the then-prevailing market price. Thus, option holders benefit most from exercising options and selling their shares when they believe the market value of the stock (*i.e.*, the price they will receive when selling the stock in the open market) is at its highest.

169. On April 19, 2007, the day before Cox exercised the first batch of 450,000 options, and just ten days before she exercised the second batch, she provided a glowing review of the sales performance of Zetia and Vytorin during the Company's first quarter 2007 earnings conference call:

> ***…Including our cholesterol franchise***, our top nine brands grew in double digits with many important growth drivers continuing to reach new highs.
>
> Turning now to our product portfolio, ***our global cholesterol franchise continued its exceptional performance with Q1 sales increasing 48% to nearly $1.2 billion. Both VYTORIN and ZETIA delivered outstanding results in the U.S. and in international markets***.
>
> In the U.S., new prescription share for the franchise reached 16.4% with ***both products continuing to set new market share highs despite the availability of a second wave of generic statins. We believe that this further validates the importance of the unique mechanism of VYTORIN, which provides superior LDL reduction through dual inhibition of the two sources of cholesterol***.
>
> ***VYTORIN's performance remains strong across many fronts, in first-line use, in switches and among specialists***. In first line, new patient starts represent more than half of all VYTORIN prescriptions demonstrating continued excellent first-line use in recently reported data. VYTORIN is the fastest-growing brand in

the market. In switches, VYTORIN remains the branded leader among switch patients. Among cardiologists, our combined new prescription share is approaching 23% and growing. ***These are all good signs of the continuing strength of prescriber confidence in VYTORIN and position us well in a post generic market.***

At last month's American College of Cardiology meeting, lowering LDL was again validated as the primary target of lipid therapy and with lower clearly better, we believe this plays right into the strength of our cholesterol franchise. Only VYTORIN provides more than a 50% LDL reduction at the usual starting dose and across the dosing range. More than Lipitor and more than Crestor.

No other product, branded or generic, delivers this kind of powerful efficacy. Managed care organizations continue to recognize this compelling value proposition and VYTORIN continues to enjoy competitive second-tier access.

Outside of the U.S., the cholesterol franchise continues to gain critical mass with sales increasing 74% to $263 million. And as you have heard, ZETIA has received marketing approval in Japan, the second-largest cholesterol market in the world with annual sales of nearly $2.2 billion.

With yesterday's approval, ZETIA has achieved the major milestone on its way to launch. We're very pleased that ZETIA will be indicated for use alone and in combination with a statin. ZETIA will become available in Japan upon national health insurance reimbursement approval.

Today less than 10 million people in Japan receive treatment for high cholesterol and with an estimated 30 million people eligible, there could be considerable growth potential longer term. ZETIA provides a whole new way to treat cholesterol, but it will take some time for Japanese physicians to become familiar with this new medicine. ***We believe that the clinical profile of ZETIA is a good fit for the Japanese market and we hope to see the growth develop well overtime.*** Along with our partner Bayer, we're excited to bring this important advance to market.

During the quarter, we also announced another step in extending our leadership position with the development of a fixed dose combination of ZETIA and atorvastatin. In partnership with Merck, this new therapy could offer an advance to patients at risk for cardiovascular disease and reflects the ongoing potential of ZETIA.

(Emphasis added).

170. On April 20, 2007, the day after providing this positive report to investors, Cox exercised 450,000 Schering stock options with a strike price of $18.20 per share. She sold the resulting shares at various prices between $30.59 and $31.06 per share. Her profit on those April 2007 transactions was $5.787 million. Ten days later, on May 1, 2007, Cox exercised 450,000 Schering stock options with a strike price of $18.50 per share, and she sold the resulting shares for $31.57 per share. Her profit on those May 2007 transactions was $5.854 million. Cox's personal profit from those April and May 2007 900,000-share sales of Schering stock totaled $11.64 million.

171. While Cox used this opportunity to exercise her options and sell her shares, Local 1500 and Colonial First were buying Schering stock in response to her optimistic report. Schering's stock price leapt from $28.55 to $30.71 (a 7.6% increase) just two days after Cox's report – when Cox exercised the first 450,000 options – and to $31.57 (a 10.6% increase) by May 1, 2007, the day she exercised the second batch of 450,000 options. By the Monday after Cox completed her trades, Schering's stock had risen to $33.05, a 16% increase. Based, in part, upon her own statements, it appears that large numbers of investors, including Local 1500 and Colonial First, believed it was a good time to buy Schering stock. Cox, who knew better, was selling.

172. Defendant Cox's Relevant Period sales of Schering stock were highly unusual in scope and timing, as measured by: (i) the amount and percentage of shares she sold; (ii) a comparison to Defendant Cox's own prior trading history and to the trading history of other Schering insiders; and (iii) the timing of her sales. Cox's sales thus provide a strong inference of scienter.

173. Defendant Cox's insider sales were unusual because her $11.64 million in profits from the sales were many times greater than her ordinary, non-incentive-based compensation. According to Schering's Proxy Statement filed with the SEC on April 23, 2008, Cox's 2007 annual salary was $1,037,500. Cox's profits from her insider stock sales were thus ***more than eleven times*** her annual salary.

174. Defendant Cox's insider sales were also unusual because the amount she sold (900,000 shares) was significantly greater than the amount of Schering stock she had previously sold, which was ***zero shares*** (according to information she has reported to the SEC).

175. Defendant Cox's sales were additionally unusual because they represented a very large percentage of her then-current stockholdings. Her sales of 900,000 shares represented approximately ***65%*** of her stockholdings at the time (including, according to Schering's Proxy Statement filed with the SEC on April 20, 2007, 408,332 shares that Defendant Cox could have acquired through the exercise of stock options within 60 days of March 28, 2007).

176. Defendant Cox's insider sales were also unusual in comparison to the amounts of stock sold by other Schering officers and directors. Whereas Defendant Cox sold 900,000 shares of Schering stock, all other Schering executives (who reported stock sales on SEC Form 4s) sold a net total of only 289,936 shares of Schering common stock during the period from July 24, 2006 to March 28, 2008. Defendant Cox's insider sales thus represented nearly ***76%*** of the total number of Schering common shares sold during this period by reporting executives.

177. Defendant Cox's insider sales were also unusual in comparison to the amounts of stock sold by all Schering reporting executives during a Control Period (from November 17, 2004 through July 23, 2006 – established for the purposes of this Complaint). During the Control

Period, all reporting Schering executives sold a total of 221,210 shares of Schering common stock. Defendant Cox's sales of 900,000 shares of Schering stock were more than ***four times*** the volume of shares sold by all Schering reporting individuals during the Control Period.

178. The timing of Defendant Cox's sales was highly unusual and suspicious because they were her first-ever sales of Schering stock, she made them ***after*** having attended several meetings about ENHANCE with the Brand Team and Drs. Veltri and Strony, ***after*** submission of the Bots Report to the Company, ***after*** the above-described CaféPharma posts, and ***after*** March 2007, the date Dr. Kastelein has stated he would have been able to release the ENHANCE results if he had been in control of the data.

179. At the time of her sales, Cox did not disclose to the investing public the unfavorable results of ENHANCE. Instead, Cox traded on her knowledge of ENHANCE for personal gain, profiting from these insider sales in excess of $11 million at a time when she was publicly praising Zetia and Vytorin.

C. Under Schering's Compensation Plans, Disclosure of the ENHANCE Results Would Have Jeopardized Significant Personal Compensation to Defendants Hassan and Cox

180. During the Relevant Period, Schering maintained a compensation structure for its top executives tied to Company performance, including share price and sales growth (which included 50% of the revenue generated by the Zetia and Vytorin joint venture). As a result of this compensation scheme, Schering executives Hassan and Cox had a direct incentive to protect Vytorin and Zetia sales to meet sales targets that would trigger lavish cash and stock bonuses for themselves. Indeed, Zetia and Vytorin accounted for between 60-70% of Schering's earnings-per-share during the Relevant Period. As a result, sales performance of those two drugs (which

was tied to the ENHANCE results) was the single greatest factor in determining whether Schering would reach the sales, earnings and stock price targets that allowed Defendants Hassan and Cox to obtain their significant incentive-based compensation. As the Company disclosed in the Proxy Statement filed with the SEC on April 23, 2008, following the release of the ENHANCE data, "because [Schering's] stock price has declined, the named executives [including Hassan and Cox] have lost significant net worth, and potential future compensation for each of them is at risk."

181. Defendants Hassan and Cox therefore had a direct and personal financial interest in suppressing and delaying the results of ENHANCE, which, upon being released, have significantly depressed Schering's overall sales, revenues and stock price. Schering's incentive compensation plans fall into two broad categories: awards based on annual goals, and awards based on long-term (*i.e.*, three- or five-year) goals, as discussed below.

1. Schering's Incentive Compensation Plans Based on Annual Goals Provided Defendants Hassan and Cox with the Motive and Opportunity to Delay and Withhold the ENHANCE Results

182. Schering has three incentive compensation plans whose payments are based on the Company meeting certain annual goals: (i) the Operations Management Team Incentive Plan (the "OMT Incentive Plan"); (ii) Performance-Contingent Options; and (iii) Deferred Stock Awards (the latter two being awarded pursuant to the 2006 Schering-Plough Corporation Stock Incentive Plan (the "2006 Stock Incentive Plan")).

183. The OMT Incentive Plan. Schering adopted the OMT Incentive Plan in 2004. The Plan provides payments to Schering executives on the Operations Management Team, which includes Defendants Hassan and Cox, who meet certain corporate performance goals established by either

the Compensation Committee (for executives who are subject to the reporting requirements of Section 16 of the Exchange Act) or by Defendant Hassan (for all other participants). Schering pays such awards for a given year in a single lump sum cash payment within 120 days after the close of the year. The corporate performance goals included both a "target" goal, at which participants would receive the "target" incentive amount, and a "maximum" goal, at which participants would receive the "maximum" incentive amount.

184. For 2007, the corporate performance goals to achieve the "target" and "maximum" cash payouts were: (i) overall sales growth of 9% for the "target" payout (and 18% for the "maximum" payout); and (ii) consolidated operating earnings per share of $1.10 per share for the "target" payout (and $1.75 per share for the "maximum" payout). In 2007, Schering met the "target" for each of those goals. In comparison to the sales growth goals of 9-18%, reported 2007 sales growth was 16.9%. In comparison to the earnings per share goals of $1.10-$1.75 per share, reported 2007 earnings per share were $1.37 per share. As a result of meeting the "target" corporate performance goals, Schering made the following OMT Incentive Plan cash payments: $4.033 million to Hassan and $1.327 million to Cox. According to the Consolidated Class Action Complaint in the Schering-Plough Class Action, this significant compensation to Hassan and Cox would have been jeopardized if sales of Zetia and Vytorin had declined by 47% or more in 2007.

185. Performance-Contingent Stock Options. Schering executive compensation also included payments of equity (rather than cash) based on annual corporate performance goals. The equity payments comprised performance-contingent stock options and deferred stock awards (discussed

below). Starting in 2005, 20% of the Schering stock options awarded to senior executives were subject to a vesting schedule made contingent on the Company's financial performance.

186. For 2007, to earn 100% of the performance-contingent stock options granted in that year, the Company needed to achieve operating earnings per share of at least $0.95 cents per share. In 2007, Schering met that goal. In comparison to the earnings per share goal of $0.95 cents per share, reported 2007 earnings per share were $1.37 cents per share. As a result, all of the 2007 performance-contingent options vested for these Defendants in the following approximate amounts: $1.797 million to Hassan and $436,178 to Cox. According to the Consolidated Class Action Complaint in the Schering-Plough Class Action, this significant compensation to Hassan and Cox would have been jeopardized if sales of Zetia and Vytorin had declined by 37% or more in 2007.

187. Deferred Stock Awards. Under the 2006 Stock Incentive Plan, Deferred Stock Units awarded to participants were credited to a Deferred Stock Account established by Schering on behalf of the participant. A participant was not a shareholder with respect to any shares underlying the Deferred Stock Units credited to his or her Deferred Stock Account until the shares were actually distributed to that participant. Under the deferred stock award program, the Compensation Committee designated performance goals for the executives. If the performance goals were not fully met, the vesting of an executive's deferred stock award was based on the degree to which the performance goals were achieved.

188. In 2007, to earn 100% of the deferred stock awards, the Company needed to achieve operating earnings per share of at least $0.95 cents per share. In 2007, Schering met that goal. In comparison to the earnings per share goal of $0.95 cents per share, reported 2007 earnings per

share were $1.37 cents per share. As a result, all of the 2007 deferred stock awards vested for these Defendants in the following approximate amounts: $3.374 million to Hassan and $992,609 to Cox. According to the Consolidated Class Action Complaint in the Schering-Plough Class Action, this significant compensation would have been jeopardized if sales of Zetia and Vytorin had declined by 37% or more in 2007.

2. Schering's Incentive Compensation Plans Based on Long-Term Goals Provided Defendants Hassan and Cox with the Motive and Opportunity to Delay and Withhold the ENHANCE Results

189. Schering also had incentive compensation plans whose payments were based on the Company meeting certain long-term (*i.e.*, three- or five-year) goals, including: (i) the Long-Term Performance Share Unit Incentive Plan; and (ii) the Transformational Performance Contingent Shares Grant.

190. Long-Term Performance Share Unit Incentive Plan. In 2007, Schering adopted a new three-year long-term performance share unit incentive plan (with a performance period ending December 31, 2009). That plan used total shareholder return (both actual and relative to a Peer Group) as a performance-based metric for one-half of the award opportunity, and sales and earnings growth metrics apply to the other half of the award opportunity. In 2007, Defendants Hassan and Cox received the following payments under the Long-Term Performance Share Unit Incentive Plan: $1.442 million to Hassan and $553,712 to Cox. According to the Consolidated Class Action Complaint in the Schering-Plough Class Action, this significant compensation would have been jeopardized if Schering's stock price had declined by 14.4% or more in 2007.

191. Transformational Performance Contingent Shares Grant. In 2004, the Schering Compensation Committee adopted the Transformational Performance Contingent Shares Grant

to recognize the contributions to the Company's turn-around of Schering's eight most senior management leaders, including Defendants Hassan and Cox. Cash awards under this one-time grant were scheduled to be earned at the end of a five-year performance period based on Schering's achievement of specific business objectives over that timeframe. Under the plan, if Schering's performance over the five-year period of January 1, 2004 through December 31, 2008 was not in the top half of the Peer Group, no payment would be earned under the grant. According to the plan, earned awards would be credited to the executive's account under the non-qualified saving plan. Under the non-qualified saving plan, the reward grows or diminishes in value as if invested in Schering common shares (with dividends reinvested). In 2007, Defendants Hassan and Cox earned the following potential awards pursuant to the Transformational Performance Contingent Shares Grant (subject to meeting the five-year goals as of December 31, 2008): $4.792 million for Hassan and $1.597 million for Cox. Schering's grudging release of the ENHANCE results in 2008 jeopardized these significant potential payments to Defendants Hassan and Cox.

192. In sum, during the Relevant Period, Defendants Hassan and Cox were motivated to delay the release of the ENHANCE results to ensure the following personal financial benefits, pursuant to the above-described incentive compensation plans:

Year	Type	Hassan	Cox
Annual			
2007	OMT Incentive Plan	$4.033 million	$1.327 million
	Performance-Contingent Stock Options	$1.797 million	$436,178
	Deferred Stock Awards	$3.374 million	$992,609
Long Term			
2007	Long-Term Performance Share Unit Incentive Plan	$1.442 million	$553,712
	Transformational Performance-Contingent Shares Grant	$4.792 million	$1.597 million
Totals		**$38.994 million**	**$13.594 million**

193. The tie between Schering's reported financial results and the Company's numerous and lucrative incentive compensation programs, collectively with all of the other facts set forth herein, raises a strong inference that Defendants Hassan and Cox had the motive to delay the release of the ENHANCE study results until they finally released them when under pressure to do so by Congress.

D. The Facts Also Support a Strong Inference that Early Analysis of the ENHANCE Data Showed the Study Was Unlikely to Detect a Statistically-Significant Benefit for Ezetimibe, Giving Defendants a Strong Motive to Delay Release of the ENHANCE Results

194. To reduce the possibility of the results being biased, clinical trials are often "double-blinded," meaning that neither the patient nor the doctor (nor, with most trials, the pharmaceutical company sponsor) knows whether the patient is in the experimental group (*i.e.*, the group taking the drug under study) or the control group (*i.e.*, the group taking placebo or another drug with known effects in the study population). Despite the obvious (and intended) limitations of blinding a clinical trial, if certain data about the population in the trial are made available, it is possible to discern useful information about the trial's results, even while the

treatment assignments remain blinded. Recognizing this, on February 11, 2008, in the Second Senate Letter, Senator Grassley wrote to Hassan that ENHANCE statisticians would not have needed to un-blind the ENHANCE data to know that the study was not likely to show a statistically-significant difference between treatment arms:

> It has come to my attention that Schering Plough and Merck would not need to unblind the data to understand that Vytorin performed no better than generic simvastatin. . . . These studies try to detect a statistically significant difference between treatment groups on the primary endpoint. Once the results are recorded, the study is then unblinded to determine which drug is the better performer. However, if the drugs performed the same, meaning there is no statistically significant difference in the treatments, then this information is apparent before the study has been unblinded.

195. Dr. Allen Taylor of Walter Reed reached the same conclusion. Dr. Taylor told Heartwire that, "Somebody had looked at the end-point examination, the IMT results, and, irrespective of group assignment, could know that a groupwise comparison of CIMT changes showed no statistically significant difference. . . . In my view, once that is known, the trial is functionally unblinded."

196. As discussed above, Schering personnel began "quality control" analyses of IMT measurements as early as 2005, the last patient visit in ENHANCE was in April 2006, Schering knew by the summer of 2006 that it was not going to get any good news from ENHANCE, and critically, the ENHANCE results, when finally released in 2008, did confirm, as Senator Grassley put it, that "the drugs performed the same, meaning there is no statistically significant difference in the treatments." Because Vytorin's failure in ENHANCE was "apparent before the study ha[d] been unblinded," the strongest, most compelling inference to be drawn is not that

delay was simply the unintended byproduct of otherwise innocent conduct, but rather that Defendants intended to and did delay the release of the ENHANCE results.

197. Indeed, well-accepted statistical methods available to Schering, Merck, and M/SP provided them with the ability to determine whether ENHANCE would be likely to show a statistically-significant change in one group's CA IMT versus the other using blinded data ***even before the trial ended.*** Schering provided an example of this methodology, commonly referred to as an "internal pilot study," on March 28, 2008 (two days before the release of the final ENHANCE results), when it disclosed that it was adding approximately 5,500 patients to IMPROVE-IT, the Company's ongoing outcomes trial designed to test whether Vytorin can reduce heart attacks more than treatment with simvastatin monotherapy. As Dow Jones reported on March 28, 2008, researchers were expanding the trial's enrollment to as many as 18,000 patients from the previous target of 12,500 because:

> The researchers said they determined that more patients were needed in order to detect whether or not Vytorin could provide a statistically significant reduction in risk of heart problems compared with one of its component drugs, simvastatin. . . . The doctors said the increase in the Improve-It study was based on "ongoing evaluation of ***blinded, aggregate cardiovascular event rates*** in the trial . . . ." Blinded typically means not knowing which patient is getting which therapy. All trial participants and leaders remain blinded to which treatment the patients are receiving, the doctors said.

(Emphasis added). Schering's ability to analyze blinded, aggregate data in IMPROVE-IT to draw a conclusion regarding the trial's capacity to show a statistically significant benefit of Vytorin over simvastatin supports a strong inference that Schering researchers could, and in fact did determine, based on blinded data, that ENHANCE would not be likely to demonstrate a statistically significant difference between treatment arms, even before the conclusion of the trial.

198. When comparing two groups of un-blinded observations with roughly bell-shaped distributions, a statistical test known as Student's t-test can be applied to determine whether the observed difference between the groups will be statistically significant. The key number is the difference between the mean outcome in each treatment group divided by the standard deviation of the observations. If that ratio (difference of means divided by standard deviation) is large, then the difference between the two treatment groups will be statistically significant. That is, the standard deviation is the "natural scale" of the data, and, for differences to be significant, they must be measured relative to that scale. How large this ratio must be to attain statistical significance depends upon the sample size.

199. For example, in the final ENHANCE carotid IMT data, first disclosed by the Company on March 30, 2008, the change outcomes were 0.0058 mm. in 320 patients receiving only simvastatin and 0.0111 mm. in 322 patients receiving simvastatin plus ezetimibe. The standard deviation ***of the change*** was about 0.068 mm. so that the key ratio was (0.0111-0.0058)/0.068 = 0.078, and favoring simvastatin alone. To attain significance, this ratio needed to be about 0.155, about twice its actual value.

200. With an internal pilot study, standard deviation can be monitored while a trial is underway, without un-blinding, assuming the two true standard deviations (parameter values) are the same. This method uses pooled data without knowledge of which treatment was received by a particular patient. Even with this limitation, analysis can extract important information about the likelihood a trial will come to a clear conclusion.

201. Because the treatment arms remain blinded, the mean and standard deviation within each group cannot be determined. However, using results seen in prior clinical trials or other data, it

is possible to establish benchmarks against which the standard deviation of pooled results from an incomplete clinical trial can be compared. An observed standard deviation that is markedly larger than the prior estimate is a signal that the trial is unlikely to yield statistically significant results to support the efficacy hypothesis being tested. In ENHANCE this approach could have been used repeatedly.

202. As alleged herein, Defendants acted with scienter in that, among other things: (i) they had access to internal data concerning ENHANCE; (ii) they knew or recklessly disregarded that the public documents and statements issued or disseminated in the name of the Company were materially false, incomplete, or misleading; (iii) they knew or recklessly disregarded that such statements or documents would be issued or disseminated to the investing public; and (iv) they knowingly or recklessly participated or acquiesced in the issuance or dissemination of such statements or documents as primary violators of the federal securities laws.

203. As officers and controlling persons of a publicly-held company whose common stock was, and is, registered with the SEC pursuant to the Exchange Act, and is traded on the NYSE, and governed by the provisions of the federal securities laws, the individual Defendants Hassan and Cox each had a duty to disseminate promptly, accurate and truthful information with respect to the Company's drug products and drug testing, its business, financial condition, and performance, growth, operations, markets, management, earnings, and present and future business prospects, and to correct any previously-issued statements that had become materially misleading or untrue, so that the market price of the Company's securities would be based upon truthful and accurate information. The individual Defendants' material misrepresentations and omissions during the Relevant Period violated these specific requirements and obligations.

204. The individual Defendants participated in the drafting, preparation, and/or approval of the various public and shareholder and investor reports and other communications complained of herein and were aware of, or recklessly disregarded, the misstatements contained therein and omissions therefrom, and were aware of or recklessly disregarded their materially false and misleading nature. Because of their senior executive and managerial positions with Schering, the individual Defendants had access to the adverse undisclosed information about Schering's business prospects and performance as particularized herein and knew (or recklessly disregarded) that these adverse facts rendered the positive representations made by or about Schering and its business issued or adopted by the Company materially false and misleading.

205. The individual Defendants because of their positions of control and authority as officers and/or directors of the Company, were able to and did control the content of the various SEC filings, press releases and other public statements pertaining to the Company during the Relevant Period. Both of the individual Defendants were provided with copies of the documents alleged herein to be misleading prior to or shortly after their issuance and/or had the ability and/or opportunity to prevent their issuance or cause them to be corrected. Accordingly, the individual Defendants are responsible for the accuracy of the public reports and releases detailed herein and are therefore primarily liable for the representations contained therein.

206. The individual Defendants, by virtue of their high-level positions with the Company, directly participated in the management of the Company, were directly involved in the day-to-day operations of the Company at the highest levels and were privy to confidential proprietary information concerning the Company and its business, operations, products, growth, and financial condition, as alleged herein. Said Defendants were involved in drafting, producing,

reviewing, and/or disseminating the false and misleading statements and information alleged herein, were aware, or recklessly disregarded, that the false and misleading statements were being issued regarding the Company, and approved or ratified these statements, in violation of the federal securities laws.

FALSE AND MISLEADING STATEMENTS AND/OR OMISSIONS

I. Defendants Made False and Misleading Statements and Omissions of Material Fact Prior to and Throughout the Relevant Period

A. The July 2006 Form 8-K, Press Release, and Earnings Call

207. Prior to the start of the Relevant Period, on July 24, 2006, Schering issued a press release announcing its financial results for the second quarter of 2006. The press release was also filed with the SEC as an exhibit to a Form 8-K. The Company reported net income of $237 million, or $0.16 cents per share on a GAAP (Generally Accepted Accounting Principles) basis, compared to a loss of $70 million during the second quarter of 2005. In particular, the press release highlighted the Company's "strong sales" of Vytorin and Zetia during the second quarter of 2006, and noted that net sales from Schering's global cholesterol joint venture (which includes Vytorin and Zetia) totaled $958 million, a considerable increase compared to net sales of $514 million in the second quarter of 2005. Specifically, the Company stated, *inter alia*, that:

> For the 2006 second quarter, key sales growth drivers included REMICADE, NASONEX and PEG-INTRON, in addition to continued solid growth of the company's cholesterol franchise. The cholesterol franchise, managed through a joint venture with Merck, comprises VYTORIN (ezetimibe/simvastatin) and ZETIA (ezetimibe). VYTORIN has been launched in more than 35 countries and ZETIA in more than 80.
>
> * * *
>
> The company noted that GAAP net sales do not include sales of the cholesterol products marketed in partnership with Merck, as

> described below. ***Global cholesterol joint venture net sales, which include VYTORIN and ZETIA, totaled approximately $958 million in the 2006 second quarter compared to net sales of $514 million in the comparable 2005 period.*** Including an adjustment of an assumed 50 percent of global cholesterol joint venture net sales, Schering-Plough's adjusted net sales for the second quarter of 2006 would have totaled $3.3 billion, an 18 percent increase, as compared to $2.8 billion on a similar adjusted basis in the second quarter of 2005.
>
> The company utilizes the equity method of accounting for its cholesterol joint venture with Merck. . . . Under the equity method, the company records its share of the income from operations (which includes milestones earned from Merck) in "Equity income from cholesterol joint venture," which totaled $355 million in the 2006 second quarter versus $170 million in the second quarter of 2005. ***The increase in equity income reflected the strong sales of VYTORIN and ZETIA in the 2006 second quarter, which were favorably impacted by a modest increase in U.S. trade inventory buying patterns***.

(Emphasis added).

208. The July 24, 2006 press release also quoted Defendant Hassan, who emphasized the purported benefits of Vytorin, as compared to competing branded and generic drugs in the cholesterol-lowering market:

> ***"While the U.S. cholesterol-lowering market adjusts to the entry of generic Zocor competition, we remain confident in the value proposition afforded by VYTORIN and ZETIA," said Hassan.*** The company pointed to head-to-head clinical trials versus Crestor, Lipitor and Zocor that have shown VYTORIN to be the most effective medicine for lowering cholesterol and getting patients to more aggressive treatment goals. Further, new recommendations from the American Heart Association and the American College of Cardiology are calling for increasingly aggressive treatment of high cholesterol for certain patients. ***"VYTORIN and ZETIA are valuable tools for doctors seeking to get their patients to goal," Hassan said, "with VYTORIN offering the added benefit of being able to get more patients to goal at the initial starting dose."***

(Emphasis added).

209. On July 24, 2006, the Company also held a conference call with securities analysts to discuss Schering's second quarter financial results. During the conference call, Defendants Hassan and Cox consistently touted the purported benefits of Vytorin, and emphasized the "fast" growth of its prescription rates and sales. Specifically, during the scripted portion of the earnings call, Hassan and Cox stated, *inter alia*, that:

> **Defendant Hassan**: "We are seeing VYTORIN and ZETIA continue to grow. ***VYTORIN was the fastest growing primary-care prescription product in the whole of the U.S. pharmaceutical market in '05, measured by sales dollars added. Let me emphasize, the whole U.S. prescription market, not just cholesterol***. We are glad to see VYTORIN continuing to be dynamic in '06. Our combined U.S. franchise is now above the 15% level for total prescriptions.
>
> Many of you have asked us about the impact of two recent generic entries, Pravachol and Zocor. ***Doctors tell me that these generics are not as effective as VYTORIN because VYTORIN can get more patients to goal, on the first try. Doctors also tell me that VYTORIN is often sparing their patients the cost and other burdens of additional visits and lab tests that, with a less effective medication, would have been needed to escalate the dose. . . .***
>
> ***You can see why this [the cholesterol-lowering market] continues to be an attractive opportunity for market expansion and especially for highly effective treatments like VYTORIN.***
>
> * * *
>
> ***The important thing is that lowering LDL has now been validated by even more outcomes trials since the joint venture was signed and this has further enhanced the value of the joint venture."***
>
> **Defendant Cox:** "Recently, the American Heart Association and the American College of Cardiology recommended more aggressive LDL management to 70 or below for patients with coronary heart disease. But as Fred [Hassan] mentioned, the majority of patients are still not at today's more challenging treatment goals. ***Older, lower efficacy statins, still usually don't get the job done, even after titration to a higher dose. With lower***

> ***clearly better, mounting clinical evidence continues to demonstrate that VYTORIN provides superior LDL reduction.***
>
> * * *
>
> ***[A]s you know, when ZETIA is added to another statin you can dramatically increase the efficacy of that statin by the addition of ZETIA. So when you look at the data that has been collected on that and recently presented for a number of products, we expect to see ZETIA growth continue because it clearly has a place in both footprints in the market both as monotherapy and as a combination therapy. So we feel quite good about ZETIA."***

(Emphasis added).

210. Moreover, in response to a question posed by a Friedman, Billings and Ramsey analyst, Cox again stressed the purported benefits of Vytorin, stating that "[t]he best outcome for patients is to lower their cholesterol as effectively as possible, as soon as possible, and that clearly shows the way towards Vytorin as the most effective therapy out there."

211. The above-referenced statements from Schering's July 24, 2006 Form 8-K, press release, and earnings call were materially misstated and omitted to state material facts required therein or necessary to make the statements contained therein not misleading, at all times throughout the Relevant Period, including, *inter alia*, that: (i) ENHANCE showed that adding ezetimibe to simvastatin resulted in no larger beneficial effects on carotid artery intima-media thickness than simvastatin monotherapy; (ii) the "strong sales" and growing market share of Zetia and Vytorin were a misleading measure of Schering's financial outlook and purported growth in view of the negative ENHANCE results; (iii) "initial data checks" in late 2005 demonstrated that the specific patient population enrolled in ENHANCE created a "higher hurdle" for demonstrating the cardiovascular benefits of ezetimibe; and (iv) by the summer of 2006, insiders with

responsibility for Schering's cholesterol franchise knew ENHANCE would not provide Schering with good news.

212. Analysts reacted positively to these material misstatements, and specifically focused on the strong sales of Vytorin and its purported benefits compared to other high- efficacy statins. For example, that same day, Prudential Equity Group issued an analyst report entitled "SGP: GOOD Q2 – RAISING EPS," stating that "[w]e think the demand for VYTORIN (and ZETIA) will remain strong following the entry of generic statins, with only a modest slowdown. Our earlier survey of managed care organizations . . . found that ***formulary decision markers view VYTORIN as the 'most differentiated' of the remaining high-efficacy statins*** . . . and the least likely to see adverse formulary changes." (Emphasis added).

B. The July 2006 Form 10-Q

213. On July 28, 2006, the Company filed its Form 10-Q for the quarter ended June 30, 2006. In addition to reiterating the financial results reported in the Company's July 24, 2006 press release, the July 2006 Form 10-Q specifically identified Vytorin and Zetia as the "primary drivers" for Schering's financial improvement. It further stated that Schering's ability to generate profits is "predominantly dependent upon the performance of the VYTORIN and ZETIA cholesterol franchise":

> ***The Company's financial situation continues to improve, as discussed below. The Company's cholesterol franchise products, VYTORIN and ZETIA, are the primary drivers of this improvement.*** . . . The Company currently expects its cholesterol franchise to continue to grow.
>
> * * *
>
> The cholesterol-reduction market is the single largest pharmaceutical category in the world. VYTORIN and ZETIA are

> competing in this market, and on a combined basis, these products have continued to grow in terms of market share during 2006. As a franchise, the two products together have captured more than 15 percent of both new and total prescriptions in the U.S. cholesterol management market (based on June 2006 IMS data). The Company believes that total prescription data is a better measure of market share during this period of generic introductions.
>
> ***During 2005 and 2006, the Company's results of operations and cash flows have been driven significantly by the performance of VYTORIN and ZETIA. As a result, the Company's ability to generate profits is predominantly dependent upon the performance of the VYTORIN and ZETIA cholesterol franchise, which dependence is expected to continue for some time.*** For the three and six months ended June 30, 2006, equity income from the cholesterol joint venture was $355 million and $666 million, respectively, and net income available to common shareholders was $237 million and $587 million, respectively.

(Emphasis added).

214. Under a subheading of the July 2006 Form 10-Q, entitled "Equity Income from Cholesterol Joint Venture," the Company further disclosed that:

> Global cholesterol franchise sales, which include sales made by the Company and the cholesterol joint venture with Merck of VYTORIN and ZETIA, totaled $965 million and $1.8 billion during the three and six months ended June 30, 2006, respectively, as compared to $518 million and $1.0 billion for the three and six months ended June 30, 2005, respectively.
>
> * * *
>
> Equity income from cholesterol joint venture totaled $355 million and $666 million in the second quarter and the first six months of 2006, respectively, as compared to $170 million and $389 million, respectively, for the same periods in 2005. ***The increase in equity income reflected the strong sales performance for VYTORIN and ZETIA during the three and six months ended June 30, 2006.***

(Emphasis added).

215. For the same reasons discussed in ¶ 211 above, in light of the ENHANCE results, the above-referenced statements from Schering's July 2006 Form 10-Q were materially misstated and omitted to state material facts required therein or necessary to make the statements contained therein not misleading, at all times throughout the Relevant Period.

216. Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. § 1350 ("SOX"), Defendant Hassan certified the July 2006 Form 10-Q, stating that the "information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Schering-Plough Corporation."

217. In addition, Hassan certified the Form 10-Q pursuant to Section 302 of SOX, stating that:

> (1) I have reviewed this quarterly report on Form 10-Q of Schering-Plough Corporation (the "registrant");
>
> (2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
>
> (3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
>
> (4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
>
> (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its

consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

(5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

218. For the same reasons discussed in ¶ 211, above, in light of the ENHANCE results, these certifications were materially misstated and omitted to state material facts required therein or

necessary to make the statements contained therein not misleading, at all times throughout the Relevant Period.

C. The October 2006 Form 8-K, Press Release, and Earnings Call

219. On October 20, 2006, the Company issued a press release announcing its financial results for the third quarter of 2006. The press release was also filed with the SEC as an exhibit to a Form 8-K. The Company reported net income of $287 million, or $0.19 cents per share on a GAAP basis, compared to reported net income of $43 million, or $0.03 cents per share, during the third quarter of 2005. In addition, the Company reported that net sales from its global cholesterol joint venture (which includes Vytorin and Zetia) totaled $1.010 billion, compared to net sales of $616 million during the third quarter of 2005.

220. The October 20 press release highlighted the Company's "strong sales" of Vytorin and Zetia during the third quarter, stating that:

> The company utilizes the equity method of accounting for its cholesterol joint venture with Merck. . . . Under the equity method, the company records its share of the income from operations in "Equity income from cholesterol joint venture," which totaled $390 million in the 2006 third quarter versus $215 million in the third quarter of 2005. ***The increase in equity income reflected the strong sales of VYTORIN and ZETIA in the 2006 third quarter.***

(Emphasis added).

221. In addition, the October 20 press release quoted Defendant Hassan, who not only characterized the cholesterol franchise as "pivotal to [Schering's] success," but emphasized that "sales of [the Company's] cholesterol joint venture have continued to grow this year, even with the U.S. introduction of new generic statins."

222. That same day, the Company held a conference call with securities analysts to discuss Schering's third quarter financial results. During the conference call, Defendant Hassan discussed Schering's growing control over the U.S. cholesterol market, stating that, "[d]uring this past quarter, Vytorin and Zetia grew 64% versus [the] prior year's quarter. Our cholesterol joint venture now commands over 15% of the U.S. cholesterol market. . . .[,] even as two generic statins enter the market." Hassan additionally stated:

> Adding ZETIA to a statin regimen provides dramatic efficacy and delivers greater LDL reduction, about as much as titrating up from Lipitor 10 milligrams to 80 milligrams, which very few people do.
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> * * *
>
> We believe our cholesterol franchise is competitively positioned for future growth with both VYTORIN and ZETIA each holding an important place along the treatment spectrum.
>
> * * *
>
> ***[VYTORIN] is just more effective than the other drugs and therefore, we are able to get good prices in Europe.***

(Emphasis added).

223. Moreover, throughout the earnings call Cox stressed the purported benefits of Vytorin, stating that ***"VYTORIN stands apart from the competition with clear superiority in lowering LDL through the dual inhibition of both sources of cholesterol."*** Cox also explained that "the continued success of this [cholesterol] franchise comes in the midst of significant uncertainty in the market with the introduction of new generic statins. ***As we have emphasized from the beginning, the value proposition for VYTORIN and ZETIA is compelling."*** (Emphasis added).

224. For the same reasons discussed in ¶ 211 above, in light of the ENHANCE results, the above-referenced statements from Schering's October 20, 2006 Form 8-K, press release and

earnings call were materially misstated and omitted to state material facts required therein or necessary to make the statements contained therein not misleading, at all times throughout the Relevant Period.

D. The October 2006 Form 10-Q

225. On October 28, 2006, the Company filed its Form 10-Q for the quarter ended September 30, 2006. In addition to reiterating the financial results reported in the October 24, 2006 press release, the October 2006 Form 10-Q specifically identified Vytorin and Zetia as the "primary drivers" for Schering's financial improvement, and stated that Schering's ability to generate profits is "predominantly dependent upon the performance of the VYTORIN and ZETIA cholesterol franchise":

> ***The Company's financial situation continues to improve, as discussed below. The Company's cholesterol franchise products, VYTORIN and ZETIA, are the primary drivers of this improvement.*** . . . The Company currently expects its cholesterol franchise to continue to grow in 2007.
>
> * * *
>
> The cholesterol-reduction market is the single largest pharmaceutical category in the world. VYTORIN and ZETIA are competing in this market, and on a combined basis, these products have continued to grow in terms of market share during 2006. As a franchise, the two products together have captured more than 15 percent of both new and total prescriptions in the U.S. cholesterol management market (based on September 2006 IMS data). During 2005 and 2006, the Company's results of operations and cash flows have been driven significantly by the performance of VYTORIN and ZETIA. As a result, the Company's ability to generate profits is predominantly dependent upon the performance of the VYTORIN and ZETIA cholesterol franchise, which dependence is expected to continue for some time. For the three and nine months ended September 30, 2006, equity income from the cholesterol joint venture was $390 million and $1.1 billion, respectively, and net income available to common shareholders was $287 million and $875 million, respectively.

(Emphasis added).

226. Under a subheading of the Form 10-Q, entitled "Equity Income from Cholesterol Joint Venture," the Company also disclosed that:

> Global cholesterol franchise sales, which include sales made by the Company and the cholesterol joint venture with Merck of VYTORIN and ZETIA, totaled $1.0 billion and $2.8 billion during the three and nine months ended September 30, 2006, respectively, as compared to $622 million and $1.6 billion for the three and nine months ended September 30, 2005, respectively.
>
> * * *
>
> Equity income from cholesterol joint venture totaled $390 million and $1.1 billion in the third quarter and the nine months ended September 30, 2006, respectively, as compared to $215 million and $605 million, respectively, for the same periods in 2005. ***The increase in equity income reflected the strong sales performance for VYTORIN and ZETIA during the three and nine months ended September 30, 2006.***

(Emphasis added).

227. For the same reasons discussed in ¶ 211 above, in light of the ENHANCE results, the above-referenced statements from Schering's October 2006 Form 10-Q were materially misstated and omitted to state material facts required therein or necessary to make the statements contained therein not misleading, at all times throughout the Relevant Period.

228. Pursuant to SOX, Defendant Hassan certified the October 2006 Form 10-Q, stating that the "information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Schering-Plough Corporation," and the "report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made,

not misleading with respect to the period covered by this report" in the form set forth in ¶ 217, above.

229. For the same reasons discussed in ¶ 211 above, in light of the ENHANCE results, these certifications were materially misstated and omitted to state material facts required therein or necessary to make the statements contained therein not misleading, at all times throughout the Relevant Period.

230. On December 19, 2006, A.G. Edwards & Sons, Inc. ("A.G. Edwards") issued an analyst report entitled "SGP: Cholesterol Franchise Key to Growth and Valuation." In that report, A.G. Edwards specifically recognized that the ***"VYTORIN/ZETIA cholesterol franchise is the most important driver of SGP's fortunes and has been critical to the [C]ompany's recent earnings turnaround."*** (Emphasis added). A.G. Edwards also stated that "[d]espite the recent introduction of generic ZOCOR, VYTORIN prescriptions have continued to grow – providing confirmation of VYTORIN's differentiation from its component parts, in our view." Notably, A.G. Edwards identified the release of the ENHANCE study as a "Key Upcoming Event" for the Company.

E. The January 2007 Morgan Stanley Conference

231. On January 3, 2007, the first day of the Relevant Period, Defendant Hassan stated during the Morgan Stanley Pharmaceutical CEOs Unplugged Conference that, "[T]he good news is that VYTORIN keeps doing well because its proposition gets better and better. ***As you look at the science that evolved***, lower LDL being better, that proposition gets better and better all the time. . . . [Doctors are] becoming more and more convinced that the lower LDL is better." (Emphasis added). For the same reasons discussed in ¶ 211 above, in light of the ENHANCE

results, this statement was materially misstated and omitted to state material facts required therein or necessary to make the statements contained therein not misleading, at all times throughout the Relevant Period.

F. The January 2007 Form 8-K, Press Release, and Earnings Call

232. On January 29, 2007, Schering issued a press release announcing its financial results for the fourth quarter and year-ended December 31, 2006. The press release was also filed with the SEC as an exhibit to a Form 8-K. The Company reported net income of $182 million for the fourth quarter (or $0.12 cents per share), and net income of $1.057 billion in net income (or $0.69 cents per share) for fiscal 2006. In addition, Schering reported that net sales from its global cholesterol joint venture (which includes Vytorin and Zetia) totaled $1.1 billion, compared to net sales of $755 million during the fourth quarter of 2005.

233. The January 29 press release also highlighted the Company's "continued strong sales" of Vytorin and Zetia, stating that:

> Under the equity method, the company records its share of the income from operations in "Equity income from cholesterol joint venture," which totaled $403 million in the 2006 fourth quarter versus $268 million in the fourth quarter of 2005. ***The increase in equity income reflected the continued strong sales of VYTORIN and ZETIA, in conjunction with Merck.***

(Emphasis added).

234. In addition, the January 29 press release includes a lengthy quote from Hassan, who praised the Company's "strong performance both for the recent quarter and for 2006." In addition, Hassan emphasized that "Schering-Plough's adjusted sales have grown more than twice

as fast as its U.S. peer group average sales," and noted that Schering is "now performing well across our businesses, including our dynamic cholesterol franchise."

235. Later that day, the Company held a conference call with securities analysts to discuss the Company's financial results for the fourth quarter and year-ended December 31, 2006. In his opening comments to investors, Defendant Hassan identified Vytorin as a "key growth driver," and explained how Schering's "strong sales" and earnings performance resulted in a "dramatic turnaround" in its free cash flow, stating:

> As a result of our strong sales and earnings performance, we've also seen a dramatic turnaround in our free cash flow. In 2003 and also in 2004, Schering-Plough had negative free cash flow of nearly $1 billion. We were seeing cash burn at an alarming rate.
>
> In '05, we basically broke even from a free cash flow perspective and in '06 for the first three quarters, we were approaching $1 billion in positive free cash flow. That was a remarkable swing.
>
> One key growth driver has certainly been our cholesterol franchise. Four years ago Schering-Plough barely registered in the cardiovascular space. Today, VYTORIN and ZETIA together are the second biggest cholesterol franchise in the world and Schering-Plough is becoming recognized as a leader in cardiovascular medical science.

236. In his scripted comments, Hassan also downplayed the impact that competing generics, such as Zocor, would have on Vytorin's continued market share, stating:

> Six months past the ZOCOR generic, we've seen that VYTORIN continued to grow market share, so we feel good that some of the more dire predictions about the impact of generic ZOCOR have not occurred. We have met that challenge.
>
> ***Now we will see the next wave of change with multiple generics. This is new territory, but we're encouraged because the proposition for VYTORIN remains strong as the evolving medical science finds that lower and lower LDL is better and better.***

(Emphasis added).

237. Further, Cox's scripted comments focused on Vytorin's growing prescription rates and purported medical benefits, specifically compared to competing generics:

> During the quarter total prescription growth for VYTORIN in the U.S. remained strong, increasing 54% versus last year, more than triple the growth of the cholesterol market. VYTORIN and ZETIA continued to grow right through the entry of generic statins.
>
> ***The facts remain the same – older, lower efficacy statins still usually don't get the job done, no matter how low the cost.*** Despite a second wave of generics entering the market, we believe that VYTORIN will continue to enjoy competitive, second tier access.
>
> Lowering LDL remains the cornerstone of lipid management. VYTORIN provides superior LDL reduction and gets more patients to goal at the initial starting dose and across the closing range, more than Lipitor, more than Crestor and more than simvastatin.

(Emphasis added).

238. Notably, during the Q&A portion of the earnings call, an analyst with Summer Street Research Partners questioned whether the deceleration of Vytorin's year-over-year growth in new prescriptions (as demonstrated by IMS prescription data) was due to Crestor, generics, or both. In response, Defendant Cox stated:

> [W]e were simply delighted that VYTORIN continued to grow so well through the launch of generic simvastatin because it wouldn't have been totally surprising if our growth had flattened out during that phase, given the fact that simvastatin could have been seen as a major competitor to VYTORIN more than any other product in the category.
>
> ***At this point, as Fred [Hassan] mentioned, the data we have demonstrating proven superiority compared to the major statins is so compelling that we feel quite confident that while LDL***

> ***remains the cornerstone of lipid management, we are very well positioned for future growth.***

(Emphasis added).

239. Also during the Q&A portion of the earnings call, an analyst with Cowen and Company inquired when Schering planned to release the results of the ENHANCE study. The Cowen and Company analyst also noted that he was "a bit concerned about this trial" because of its "challenging design and end point." In response, as set forth above, Defendant Hassan downplayed the significance of the study's findings, noting that it applied only to "a very special category of patients":

> ***As far as ENHANCE is concerned, there will be no announcement at the ACC [in March 2007]. We want to do the right thing in terms of the measurements in this very, very complex protocol.*** We're in no rush to get a marketing thing out of this.
>
> We're really doing this in the right way, and if it helps, if it advances science, that will be great for the patients. As you know, ***these are very special, these are a very special category of patients and they're not mainstream patients, so it would not be a good comparison to compare it with the trial that's going to read out from Crestor.***
>
> ***The study for ENHANCE has closed and we are in the process of working on the data*** and making good progress but we want to do it the right way.

(Emphasis added).

240. The above-referenced statements from Schering's January 29, 2007 Form 8-K, press release and earnings call were materially misstated and omitted to state material facts required therein or necessary to make the statements contained therein not misleading, at all times throughout the Relevant Period, including, *inter alia*, that: (i) ENHANCE showed that adding ezetimibe to simvastatin resulted in no larger beneficial effects on carotid artery intima-media

thickness than simvastatin monotherapy; (ii) the "strong sales" and growing market share of Zetia and Vytorin were a misleading measure of Schering's financial outlook and purported growth in view of the negative ENHANCE results; (iii) "initial data checks" in late 2005 demonstrated that the specific patient population enrolled in ENHANCE created a "higher hurdle" for demonstrating the cardiovascular benefits of ezetimibe; (iv) by the summer of 2006, insiders with responsibility for Schering's cholesterol franchise knew ENHANCE would not provide Schering with good news; and (v) in January 2007, an independent consultant retained by Schering had determined that the quality of the ENHANCE data was "fine; *i.e.*, no better, no worse than what [had] been reported in [other similar studies]," and that the data were therefore suitable for publication.

241. Analysts reacted positively to these material misstatements. For example, on January 29, 2007, A.G. Edwards issued an analyst report stating that "we see the continued growth that we forecast as a sign of the strength of SGP's underlying product portfolio, led by the cholesterol drugs ZETIA and VYTORIN and the evolution of the company's cost-base / infrastructure. ***We remain positive on the outlook for ZETIA / VYTORIN and continue to view VYTORIN as the LDL cholesterol 'gold standard' in terms of its impressive efficacy in lowering LDL on an absolute level."*** (Emphasis added). A.G. Edwards also continued to identify the results of ENHANCE as a "Key Upcoming Event" for the Company in 2007.

242. Moreover, on January 30, 2007, Prudential Equity Group LLP issued an analyst report entitled "Q4 Post-View – Quiet Story But Decent Outlook . . . Raising EPS." Similar to A.G. Edwards, Prudential characterized the ENHANCE study as an "important trial," and noted that, in the analyst's opinion, the study would show "favorable findings":

> In terms of catalysts for 2007, at present there does not appear to be many that are significant. ***Data from an important trial with VYTORIN, called the ENHANCE trial, should be in hand during 1H'07***. . . . ENHANCE was, in our opinion, probably a trial that did not need to be run because the stakes will be high. . . . There is probably equal upside/downside to VYTORIN based on the outcome of this trial. ***We think it will show favorable findings.***

(Emphasis added).

G. The Form 10-K Filed in February 2007

243. On February 28, 2007, the Company filed its Form 10-K with the SEC for the fiscal year-ended December 31, 2006, signed by Defendant Hassan. The Form 10-K reiterated the financial results reported in Schering's January 2007 press release. The statements in the Form 10-K discussed below were materially misstated and omitted to state material facts required therein or necessary to make the statements contained therein not misleading.

244. The Form 10-K stated that Schering's "cholesterol franchise" is: "ZETIA, a novel cholesterol-absorption inhibitor discovered by Schering-Plough scientists, for use as monotherapy or in combination with either statins or fenofibrate to lower cholesterol;" and "VYTORIN, a cholesterol-lowering tablet combining the dual action of ZETIA and Merck & Co., Inc.'s statin, Zocor." Schering's disclosures relating to Zetia and Vytorin detail the importance of these drugs to Schering's financial health.

245. In Item 7, under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations," under the subheading, "2006 Results – Highlights of Schering-Plough's performance in 2006," the Form 10-K stated: "Global sales of Schering-Plough's cholesterol franchise products, VYTORIN and ZETIA, made by the cholesterol joint

venture with Merck & Company, Inc. (Merck) continued to grow in 2006 and significantly contributed to Schering-Plough's improved operating results and cash flow."

246. Also under Item 7, under the subheading, "Cholesterol Franchise," the Form 10-K stated:

> Schering-Plough's cholesterol franchise products, VYTORIN and ZETIA, are managed through a joint venture between Schering-Plough and Merck for the treatment of elevated cholesterol levels. ***ZETIA is Schering-Plough's novel cholesterol absorption inhibitor.*** VYTORIN is the combination of ZETIA and Zocor, Merck's statin medication . . .
>
> A material change in the sales or market share of Schering-Plough's cholesterol franchise would have a significant impact on Schering-Plough's results of operations and cash flows. In order to maintain and enhance its infrastructure and business, Schering-Plough must continue to increase profits. ***This increased profitability is largely dependent upon the performance of Schering-Plough's cholesterol franchise.***
>
> The cholesterol-reduction market is the single largest pharmaceutical category in the world. VYTORIN and ZETIA are competing in this market and, on a combined basis, these products continued to grow in terms of market share during 2006. As a franchise, the two products together have captured more than 15 percent of total prescriptions for the U.S. cholesterol management market (based on January 2007 IMS data).

(Emphasis added).

247. Moreover, in its discussion of operating results, under the sub-heading, "Equity Income from Cholesterol Joint Venture," the Form 10-K stated:

> Global cholesterol franchise sales, which include sales of VYTORIN and ZETIA, made by the cholesterol joint venture with Merck and Schering-Plough totaled $3.9 billion . . . The sales growth in 2006 was due to an increase in market share . . . As a franchise, the two products combined have captured more than 15 percent of total prescriptions in the U.S. cholesterol management market (based on January 2007 IMS data).

248. Under the heading "2007 OUTLOOK," the Form 10-K stated:

> Currently, the U.S. cholesterol lowering market is adjusting to the entry into the market of multiple generic forms of competing cholesterol products. ***Despite the introduction of new innovative competing treatments and generic versions of competing products, Schering-Plough continues to anticipate that sales from VYTORIN and ZETIA will grow in 2007.*** The decisions of government entities, managed care groups and other groups concerning formularies and reimbursement policies could negatively impact the dollar size and/or growth of the cholesterol management market, including VYTORIN and ZETIA.

(Emphasis added).

249. For the same reasons discussed in ¶ 240 above, in light of the ENHANCE results, the above-referenced statements from Schering's Form 10-K filed February 28, 2007 were materially misstated and omitted to state material facts required therein or necessary to make the statements contained therein not misleading, at all times throughout the Relevant Period.

250. Pursuant to SOX, Defendant Hassan certified the Form 10-K filed February 28, 2007, stating that the "information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of Schering-Plough Corporation," and the "report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report" in the form set forth in ¶ 217 above. For the same reasons discussed in ¶ 240 above, in light of the ENHANCE results, these certifications were materially misstated and omitted to state material facts required therein or necessary to make the statements contained therein not misleading, at all times throughout the Relevant Period.

H. The April 2007 Letter to Shareholders

251. In a letter to Schering shareholders dated April 13, 2007, at the beginning of Schering's 2006 Financial Report, Defendant Hassan wrote:

> Looking at the product areas, we drove growth of the cholesterol franchise with our partner Merck, achieving 60 percent higher sales versus 2005 for VYTORIN and ZETIA together. We delivered this performance even as two generic statins entered the U.S. market. We expect this franchise to continue to grow in 2007, as medical science has consistently demonstrated that the more you can lower LDL ("bad") cholesterol, the better. And no medicine does this more effectively than VYTORIN.

These statements were materially false and misleading and omitted material facts because the results of ENHANCE posed a direct and existing threat to sales of Zetia and Vytorin, Schering's most profitable products, and because the ENHANCE results raised serious questions about whether lower LDL cholesterol, as lowered by Zetia and Vytorin was in fact better for patients. Yet no information about the ENHANCE results was disclosed to the public.

I. The April 2007 Form 8-K, Press Release, and Earnings Call

252. On April 19, 2007, the Company issued a press release announcing its financial results for the first quarter of 2007. The press release was also filed with the SEC as an exhibit to a Form 8-K. Schering reported net income of $543 million, or $0.36 cents per common share, as compared to net income of $350 million, or $0.24 cents per common share, in the first quarter of 2006. In addition, the Company reported that net sales from its global cholesterol joint venture (which includes Vytorin and Zetia) totaled $1.2 billion in the first quarter, a 48 percent increase compared to net sales of $778 million in the first quarter of 2006.

253. The April 19 press release also quoted Defendant Hassan, who emphasized the Company's "10 consecutive quarters of double-digit adjusted sales growth on a year-over-year basis" and its emergence as a "leader" in cardiovascular care:

> "Schering-Plough has now delivered 10 consecutive quarters of double-digit adjusted sales growth on a year-over-year basis," said Hassan. "We are growing our core businesses across all major geographic regions. We have sustained the strength of our cholesterol, respiratory, immunology and oncology franchises. Our Animal Health and Consumer Health Care businesses are also growing. Our strategy of growing the top line while maintaining financial discipline is clearly paying off – with higher bottom-line earnings and growing financial headroom."
>
> * * *
>
> ***In cardiovascular care, Schering-Plough "is emerging as a leader, both in the marketplace and in clinical research,"*** said Hassan.

(Emphasis added).

254. That same day, the Company held a conference call with securities analysts to discuss its financial results for the first quarter of 2007. During the scripted portion of the earnings call, Defendants Hassan and Cox continued to stress the still-growing sales of Vytorin and Zetia, notwithstanding a "new wave" of generics:

> **Defendant Hassan**: "Adjusted for our assumed 50% share of VYTORIN and ZETIA, that is 21% adjusted growth versus the same quarter last year. We continue[d] to grow VYTORIN and ZETIA despite the new wave of generics that has recently entered the market. As we have said before, physicians and their patients are following ***the evolving medical science; evolving medical science that is indicating that lower LDL cholesterol is better."***
>
> **Defendant Cox**: "[O]ur global cholesterol franchise continued its exceptional performance with Q1 sales increasing 48% to nearly $1.2 billion. Both VYTORIN and ZETIA delivered outstanding results in the U.S. and in international markets.

> In the U.S., new prescription shares for the franchise reached 16.4% with both products continuing to set new market share highs despite the availability of a second wave of generic statins. ***We believe that this further validates the importance of the unique mechanism of VYTORIN, which provides superior LDL reduction through dual inhibition of the two sources of cholesterol.***
>
> VYTORIN's performance remains strong across many fronts, in front-line use, in switches and among specialists. In first line, new patient starts represent more than half of all VYTORIN prescriptions demonstrating continued excellent first-line use in recently reported data. VYTORIN is the fastest-growing brand in the market. In switches, VYTORIN remains the branded leader among switch patients. Among cardiologists, our combined new prescription share is approaching 23% and growing. ***These are all good signs of the continuing strength of prescriber confidence in VYTORIN and position us well in a post generic market.***
>
> At last month's American College of Cardiology meeting, lowering LDL was again validated as the primary target of lipid therapy and with lower clearly better, we believe this plays right into the strength of our cholesterol franchise. ***Only VYTORIN provides more than a 50% LDL reduction at the usual starting dose and across the closing range.*** More than Lipitor and more than Crestor.
>
> ***No other product, branded or generic, delivers this kind of powerful efficacy.*** Managed care organizations continue to recognize this compelling value proposition and VYTORIN continues to enjoy competitive second-tier access."

(Emphasis added).

255. During the Q&A portion of the earnings call, an analyst with Prudential Equity noted that the results of ENHANCE "could be fairly important to [the] VYTORIN franchise," and questioned whether Schering was "worried" about the outcome. In response, Hassan again tried to downplay the importance of ENHANCE, stating that it "is a surrogate market trial in a very special population with very special doses." Instead, Hassan directed the analyst to the IMPROVE-IT trial, which he characterized as "more of an outcomes trial." Notwithstanding his

attempt to deflect attention away from ENHANCE, Hassan still emphasized that "[t]he overall regression curve in terms of LDL, lower LDL, is better, is being proven in numerous studies, ***so we are pretty confident about the overall pattern of data for VYTORIN."*** (Emphasis added).

256. For the same reasons discussed in ¶ 240 above, in light of the ENHANCE results, the above-referenced statements from Schering's April 19, 2007 Form 8-K, press release, and earnings call were materially misstated and omitted to state material facts required therein or necessary to make the statements contained therein not misleading, at all times throughout the Relevant Period. In addition, Hassan's attempt to downplay ENHANCE was materially misleading in that he omitted to state that ENHANCE had failed to demonstrate that VYTORIN had any statistically-significant difference in the treatment of atherosclerosis compared to simvastatin.

J. The April 2007 Form 10-Q

257. On April 27, 2007, the Company filed its Form 10-Q for the first quarter of 2007 with the SEC. The Company's April 2007 Form 10-Q reiterated the financial results reported in the April 19, 2007 press release, and specifically recognized under a subheading entitled "Outlook" that "Schering-Plough anticipates that sales from VYTORIN and ZETIA will grow in 2007."

258. Under Item 2 of the Form 10-Q, entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations," the Company stated that:

> ***Global sales of Schering-Plough's cholesterol franchise products, VYTORIN and ZETIA, continued to grow in 2007.***
>
> ***
>
> A material change in the sales or market share of Schering-Plough's cholesterol franchise would have a significant impact on

> Schering-Plough's results of operations and cash flows. In order to maintain and enhance its infrastructure and business, Schering-Plough must continue to increase profits. ***This increased profitability is largely dependent upon the performance of Schering-Plough's cholesterol franchise.***

(Emphasis added).

259. Similarly, under the heading, "Cholesterol Franchise," the April 2007 Form 10-Q stated:

> Schering-Plough's cholesterol franchise products, VYTORIN and ZETIA, are managed through a joint venture between Schering-Plough and Merck for the treatment of elevated cholesterol levels. ZETIA is Schering-Plough's novel cholesterol absorption inhibitor. VYTORIN is the combination of ZETIA and Zocor, Merck's statin medication . . .
>
> The cholesterol-reduction market is the single largest pharmaceutical category in the world. VYTORIN and ZETIA are competing in this market, and on a combined basis, these products continued to grow in terms of market share during the first three months of 2007. A material change in the sales or market share of Schering-Plough's cholesterol franchise would have a significant impact on Schering-Plough's results of operations and cash flows. In order to maintain and enhance its infrastructure and business, Schering-Plough must continue to increase profits. ***This increased profitability is largely dependent upon the performance of Schering-Plough's cholesterol franchise.***

(Emphasis added).

260. In addition, the Company reported under the heading "Equity income from cholesterol joint venture" that:

> Global cholesterol franchise sales, which include sales of VYTORIN and ZETIA, made by the cholesterol joint venture with Merck and Schering-Plough for the three months ended March 31, 2007 and 2006 totaled $1.2 billion and $786 million, respectively. The sales growth in 2007 was due to an increase in market share.
>
> * * *

> Equity income from cholesterol joint venture totaled $487 million and $311 million for the three months ended March 31, 2007 and 2006, respectively. ***The increase in 2007 equity income as compared to 2006 reflects continued strong sales of VYTORIN and ZETIA."***

(Emphasis added).

261. For the same reasons discussed in ¶ 240 above, in light of the ENHANCE results, the above-referenced statements from Schering's April 2007 Form 10-Q were materially misstated and omitted to state material facts required therein or necessary to make the statements contained therein not misleading, at all times throughout the Relevant Period.

262. Pursuant to SOX, Defendant Hassan certified the April 2007 Form 10-Q, stating that the "information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Schering-Plough Corporation," and "this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report" in the form set forth in ¶ 217 above. For the same reasons discussed in ¶ 240 above, in light of the ENHANCE results, these certifications were materially misstated and omitted to state material facts required therein or necessary to make the statements contained therein not misleading, at all times throughout the Relevant Period.

K. The June 2007 Goldman Sachs Conference

263. On June 14, 2007, Bertolini and Thomas P. Koestler, a Schering Executive Vice President and President of SPRI ("Koestler"), presented to analysts at Goldman Sachs's Global Healthcare Conference. During the scripted portion of his presentation, Bertolini noted that

"VYTORIN is the fastest growing branded product in the cholesterol-lowering market and ZETIA also continues to grow. In fact, since June of [2006], [Schering's] franchise has gained one full market share point even in the face of generic simvastatin."

264. During the Q&A portion of the conference, an analyst with Goldman Sachs questioned whether ENHANCE and other ongoing trials would drive the utilization of Vytorin. In response, Koestler claimed, "we haven't seen the data yet." Koestler also asserted that ENHANCE is a "very complicated" trial, and requires "roughly 18,000 to 20,000 views [of the digital images] . . . before you get to the answer to the study."

265. For the reasons discussed in ¶ 240 above, in light of the ENHANCE results, the above-referenced statements from the Goldman Sachs conference on June 14, 2007 were materially misstated and omitted to state material facts required therein or necessary to make the statements contained therein not misleading, at all times through the Relevant Period.

L. The July 2007 Form 8-K, Press Release, and Earnings Call

266. On July 23, 2007, the Company issued a press release to announce its financial results for the second quarter of 2007. The press release was also filed with the SEC as an exhibit to a Form 8-K. The Company reported net income of $517 million, or $0.34 cents per share, compared to net income of $237 million, or $0.16 cents per share, during the second quarter of 2006. In addition, the Company reported that net sales from its global cholesterol joint venture (which includes Vytorin and Zetia) totaled $1.2 billion in the second quarter of 2007, a 30 percent increase compared to net sales of $958 million in the comparable 2006 period.

267. The press release also quoted Defendant Hassan, who emphasized the Company's continued growth, particularly with respect to the market share of Vytorin:

> Reviewing second quarter results, Hassan emphasized, "We're growing across a broad front. Seven out of our 10 largest-selling products, including VYTORIN and ZETIA, posted double-digit sales growth for the quarter," he said. ***"And even with the recent arrival of multi-source U.S. generic competition, our cholesterol franchise continues to be dynamic. In fact, VYTORIN and ZETIA are the only major cholesterol-lowering brands to have grown U.S. market share in 2007."***

(Emphasis added).

268. Later that day, the Company held an earnings call with securities analysts to discuss the Company's financial results for the second quarter of 2007. During the scripted portion of the earnings call, Defendants Hassan and Cox continued to highlight the growing sales, market share and purported benefits of Vytorin:

> **Defendant Hassan**: "We continue to grow VYTORIN and ZETIA sales even in the face of the new wave of generic statins. In fact, ***VYTORIN and ZETIA are the only major cholesterol-lowering brands that have gained market share in total prescriptions since the end of '06."***
>
> **Defendant Cox**: "[O]ur global cholesterol franchise delivered another impressive quarter with global franchise sales increasing 34% to nearly $1.3 billion. . . . In the U.S., VYTORIN and ZETIA continue to grow despite the availability of multi-source generics. ***New prescription growth for the franchise remains strong, increasing 20% versus the prior year, and more than double growth of the entire cholesterol market. Both VYTORIN and ZETIA set new market share highs and remain the only branded growth products in the LDL category.***
>
> ***As we have anticipated, clinical practice continues to shift towards more aggressive LDL management. With lower clearly better only VYTORIN provides more than a 50% LDL reduction at the usual starting dose through the dual inhibition of both sources of cholesterol. VYTORIN simply gets more patients to goal at the initial starting dose and across the dosing range. First line therapy continues to represent the majority of VYTORIN business. VYTORIN is also the brand of choice for patients needing to upgrade their medication for greater efficacy.***

> We believe both VYTORIN and ZETIA are well-positioned in the post-generic marketplace. Outside of the U.S., sales from the cholesterol franchise increased 83% to $330 million. The big news, of course, is the June launch of ZETIA in Japan, the second largest cholesterol market in the world."

(Emphasis added).

269. During the Q&A portion of the conference call, an analyst with Leerink Swann asked for an update on when Schering planned to announce the results of ENHANCE. In response, Alex Kelly, Schering's Vice President of Investor Relations, stated that the "trial is still blinded and the data analysis is still ongoing by a third party." Kelly also downplayed ENHANCE compared to IMPROVE-IT, stating that "[t]he big trial is the IMPROVE-IT trial and that's the real hard outcomes trial that we're looking at. While ENHANCE is a surrogate marker trial, the IMPROVE-IT trial is the real hard end point trial looking at patients with acute coronary syndrome."

270. The above-referenced statements from Schering's July 23, 2007 Form 8-K, press release and earnings call were materially misstated and omitted to state material facts required therein or necessary to make the statements contained therein not misleading, at all times throughout the Relevant Period, including, *inter alia*, that: (i) ENHANCE showed that adding ezetimibe to simvastatin resulted in no larger beneficial effects on carotid artery intima-media thickness than simvastatin monotherapy; (ii) the "strong sales" and growing market share of Zetia and Vytorin were a misleading measure of Schering's financial outlook and purported growth in view of the negative ENHANCE results; (iii) "initial data checks" in late 2005 demonstrated that the specific patient population enrolled in ENHANCE created a "higher hurdle" for demonstrating the cardiovascular benefits of ezetimibe; (iv) by the Summer of 2006, insiders with responsibility for

Schering's cholesterol franchise knew ENHANCE would not provide Schering with good news; (v) in January 2007, an independent consultant retained by Schering had determined that the quality of the ENHANCE data was "fine; *i.e.*, no better, no worse than what [had] been reported in [other similar studies]," and that the data were therefore suitable for publication"; and (vi) in July 2007, the Company was specifically apprised by the ENHANCE Principal Investigator that there was no good reason to continue delaying publication of the results.

M. The July 2007 Form 10-Q

271. On On July 27, 2007, the Company filed its Form 10-Q for the second quarter of 2007 with the SEC. The July 2007 Form 10-Q reiterated the Company's financial results reported in the Company's July 23, 2007 press release. Under a subheading of the Form 10-Q entitled "Outlook," the Company noted that it "continues to anticipate that sales from VYTORIN and ZETIA will grow in 2007."

272. Similarly, under the heading, "Cholesterol Franchise," the July 2007 Form 10-Q stated:

> Schering-Plough's cholesterol franchise products, VYTORIN and ZETIA, are managed through a joint venture between Schering-Plough and Merck for the treatment of elevated cholesterol levels. ZETIA is Schering-Plough's novel cholesterol absorption inhibitor. VYTORIN is the combination of ZETIA and Zocor, Merck's statin medication. . . .
>
> The cholesterol-reduction market is the single largest pharmaceutical category in the world. VYTORIN and ZETIA are competing in this market, and on a combined basis, these products continued to grow in terms of market share during the first three months of 2007. A material change in the sales or market share of Schering-Plough's cholesterol franchise would have a significant impact on Schering-Plough's results of operations and cash flows. In order to maintain and enhance its infrastructure and business, Schering-Plough must continue to increase profits. ***This increased profitability is largely dependent upon the performance of Schering-Plough's cholesterol franchise.***

(Emphasis added).

273. In addition, under a subheading of the Form 10-Q entitled "Equity Income from Cholesterol Joint Venture," the Company reported that:

> Sales of the Merck/Schering-Plough Cholesterol Partnership for the three and six months ended June 30, 2007 totaled $1.3 billion and $2.4 billion, respectively, as compared to $973 million and $1.8 billion for the three and six months ended June 30, 2006. ***The sales growth in 2007 was due to an increase in market share.***
>
> * * *
>
> Equity income from cholesterol joint venture totaled $490 million and $978 million for the three and six months ended June 30, 2007, respectively, as compared to $355 million and $666 million for the three and six months ended June 30, 2006, respectively. ***The increase in 2007 equity income as compared to 2006 reflects continued strong sales of VYTORIN and ZETIA.***

(Emphasis added).

274. For the same reasons discussed in ¶ 270 above, in light of the ENHANCE results, the above-referenced statements from the July 2007 Form 10-Q were materially misstated and omitted to state material facts required therein or necessary to make the statements contained therein not misleading, at all times throughout the Relevant Period.

275. Pursuant to SOX, Defendant Hassan certified the July 2007 Form 10-Q, stating that the "information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Schering-Plough Corporation," and the "report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report" in the form set forth in ¶ 217

above. For the same reasons set forth in ¶ 270 above, in light of the ENHANCE results, these certifications were materially misstated and omitted to state material facts required therein or necessary to make the statements contained therein not misleading, at all times throughout the Relevant Period.

N. The September 2007 Merrill Lynch Conference

276. On September 19, 2007, Schering Vice President of Investor Relations Alex Kelly presented at the Merrill Lynch Global Pharmaceutical, Biotech & Medtech Conference held in London, England. In his scripted comments, Kelly emphasized the continued growth of Vytorin's market share, stating that:

> [S]o far, in 2007 – this is through August 2007 – VYTORIN and ZETIA are the only two major brands to be growing market share. In fact, we're picking up just short of about a tenth of a share point a month on an average basis so far this year. ***So what's driving it? Number one, we have a very strong profile for the products. VYTORIN AND ZETIA are unique. They offer a dual mechanism of treating cholesterol.*** Because ZETIA inhibits cholesterol absorption in the intestines, it works in a different way from the other statins. ***When you combine ZETIA with simvastatin to make VYTORIN, you get this dual mechanism that no other product has. So that's number one. The science is favoring VYTORIN and ZETIA.***

(Emphasis added).

277. During the Q&A portion of the investor conference, an analyst with Merrill Lynch asked for an update on ENHANCE. In response, Kelly pointed to several purported reasons as to why ENHANCE is "unusual" and "cumbersome," stating as follows:

> ENHANCE is a surrogate marker trial that we have underway comparing high-dose VYTORIN, 10 mg of ZETIA plus 80 mg of simvastatin, versus 80 mg of simvastatin. ***So it's a very high dose, somewhat unusual. It's not a very commonly used dose in the***

> ***marketplace. And it's also in a high-risk population with familial hypercholesterolemia, so very high-risk patients***. . . .
>
> So with this trial we're undertaking, ***so it's a somewhat cumbersome trial***, because we are looking at more than 700 patients in this trial, and each patient will receive many, many different scans of their carotid artery. ***So as a result we'll probably have more than 40,000 scans that have to be read in this trial, and that's why it's taking a bit of time to get this trial wrapped up. The data is still blinded and is still under review by the outside firm that's analyzing those scans.*** So we look forward to presenting that data as soon as possible, but at this point . . . the data is still being analyzed.

(Emphasis added).

278. For the same reasons discussed in ¶ 270 above, in light of the ENHANCE results, the above-referenced statements from the Merrill Lynch conference on September 19, 2007 were materially misstated and omitted to state material facts required therein or necessary to make the statements contained therein not misleading, at all times throughout the Relevant Period.

O. The October 2007 Form 8-K, Press Release, and Earnings Call

279. On October 22, 2007, the Company issued a press release announcing its financial results for the third quarter of 2007. The press release was also filed with the SEC as an exhibit to a Form 8-K. The Company reported net income of $713 million, or $0.45 cents per share, compared to net income of $287 million, or $0.19 cents per share, during the third quarter of 2006. In addition, the Company reported that net sales from its global cholesterol joint venture (which includes Vytorin and Zetia) totaled $1.3 billion in the third quarter, a 26 percent increase compared to net sales of $1.0 billion in the comparable 2006 period.

280. The press release also quoted Defendant Hassan, who emphasized the Company's "12th consecutive quarter of double-digit adjusted sales growth." In addition, recognizing the

Company's dissolution of a five-year FDA consent decree in August 2007, Hassan proclaimed that Schering is "a company that stands out for injecting quality, compliance and business integrity into [its] DNA."

281. Later that day, the Company held a conference call with securities analysts to discuss Schering's third quarter financial results. During the scripted portion of the conference call, Defendants Hassan and Cox continued to highlight the purported benefits of Vytorin, as well as its still-growing sales figures even in the face of new generics:

> **Defendant Hassan**: "Seven out of our Top 10 products continue to grow double digits, including ZETIA and VYTORIN, our cholesterol franchise continued to be a driver. We continued to grow market share in a very big market.
>
> VYTORIN and ZETIA are the only major brands that have continued to grow their market share during the disruption that began in December '06 that was caused by multi-source generics. The lower is better story continues. ***Evolving medical science continues to find that reaching lower and lower goals for LDL is better for patients and VYTORIN and ZETIA provide very good options."***
>
> **Defendant Cox:** "[O]ur global cholesterol franchise continued its strong performance with sales increasing 27% to nearly $1.3 billion, with growth well balanced in the U.S. and international markets. You will recall that our franchise includes sales from the joint venture and Schering-Plough only territories.
>
> ***In the U.S., VYTORIN and ZETIA remained the fastest growing brands with total prescriptions for the franchise increasing 17% versus the prior year, growing more than twice as fast as the cholesterol market. Among LDL lowering brands, VYTORIN and ZETIA are the only two major products to grow market share this year.*** Our franchise is uniquely positioned to get more patients to their LDL goal. Managed care organizations have recognized this important value and continue to provide competitive second tier access for both VYTORIN and ZETIA, despite the availability of multi-source generics."

(Emphasis added).

282. For the same reasons discussed in ¶ 270 above, in light of the ENHANCE results, the above-referenced statements from Schering's October 22, 2007 Form 8-K, press release and earnings call were materially misstated and omitted to state material facts required therein or necessary to make the statements contained therein not misleading, at all times throughout the Relevant Period.

P. The October 2007 Form 10-Q

283. On October 26, 2007, Defendants filed the Company's Form 10-Q for the quarter ended September 30, 2007 with the SEC. In addition to reiterating the financial results reported in the Company's October 22, 2007 press release, the Company recognized under the subheading for "Equity Income from Cholesterol Joint Venture" that "[t]he increase in 2007 equity income as compared to 2006 reflects continued strong sales of VYTORIN and ZETIA." Under a subheading of the October 2007 Form 10-Q entitled "Outlook," the Company also reported that it "anticipates that sales from VYTORIN and ZETIA will continue to grow in the fourth quarter of 2007 and in 2008."

284. The Form 10-Q also stated, under the heading "Equity income from cholesterol joint venture":

> Sales of the Merck/Schering-Plough cholesterol joint venture for the three and nine months ended September 30, 2007 totaled $1.3 billion and $3.7 billion, respectively, as compared to $1.0 billion and $2.8 billion for the three and nine months ended September 30, 2006. ***The sales growth in 2007 was due to an increase in market share.***
>
> * * *
>
> Equity income from cholesterol joint venture totaled $506 million and $1.5 billion for the three and nine months ended September 30, 2007, respectively, as compared to $390 million and $1.1 billion

> for the three and nine months ended September 30, 2006, respectively. ***The increase in 2007 equity income as compared to 2006 reflects continued strong sales of VYTORIN AND ZETIA.***

(Emphasis added).

285. For the same reasons discussed in ¶ 270 above, in light of the ENHANCE results, the above-referenced statements from the October 2007 Form 10-Q were materially misstated and omitted to state material facts required therein or necessary to make the statements contained therein not misleading, at all times throughout the Relevant Period.

286. Pursuant to SOX, Defendant Hassan certified the October 2007 Form 10-Q, stating that the "information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Schering-Plough Corporation," and the "report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report" in the form set forth in ¶ 217 above. For the same reasons discussed in ¶ 270 above, in light of the ENHANCE results, these certifications were materially misstated and omitted to state material facts required therein or necessary to make the statements contained therein not misleading, at all times throughout the Relevant Period.

Q. The November 2007 Press Release

287. On November 19, 2007, Defendant M/SP issued a press release entitled "Merck/Schering-Plough Pharmaceuticals Provides Update on ENHANCE Trial." Specifically, the November 19 press release stated that an independent expert panel purportedly made a

recommendation to change the primary endpoint of ENHANCE to "expedite the reporting of the study findings":

> [A]n independent panel of clinical and biostatics experts was convened on Friday, November 16, 2007 to offer advice about the prospective analysis of the ENHANCE trial. . . .
>
> ***The independent panel recommended focusing the primary endpoint to the common carotid artery to expedite the reporting of the study findings.*** Merck/Schering-Plough now anticipates that these results of the ENHANCE study will be presented at the American College of Cardiology meeting in March 2008.
>
> ***While the clinical portion of the ENHANCE study is complete, the study remains blinded and the data are now being analyzed.*** The rigorous study design and analytical process specified in the study protocol require examinations of more than 40,000 scans of the arterial intima-media thickness (IMT) of the carotid and femoral arteries collected in eighteen multi-national study sites. This has been time consuming and taken longer than originally anticipated because the analysis, observations of variability in some of the data were detected as part of the validation / data review procedures. ***Such potentially confounding observations are not unusual in studies of this kind.***

(Emphasis added). This statement was materially false and misleading because it falsely attributed to the expert panel (rather than to Defendants) the decision to change the primary endpoint of ENHANCE and failed to disclose the adverse results of ENHANCE.

288. The November 19 press release also purportedly quoted Dr. Kastelein, the lead investigator of the ENHANCE study, as stating that:

> It is critically important for researchers to take the appropriate time and rigor to conduct clinical trials, analyze data and report study results. ***The ENHANCE trial is complex and is being conducted with great care. . . . We view the expert's panel's recommendation to narrow the primary endpoint to the common carotid artery as helpful,*** and we will continue to expedite the completion of ENHANCE and reporting of its results, while ensuring the integrity of the data.

(Emphasis added). This statement was false and misleading because it falsely attributed to the expert panel (rather than to Defendants) the decision to change the primary endpoint of ENHANCE. Dr. Kastelein also effectively repudiated this statement after Schering later announced it would not modify ENHANCE's pre-specified endpoint.

289. Analysts relied on the November 19 press release with respect to the expert panel's recommendations and the purported problems affecting the completion of the study. On November 20, 2007, Cowen and Company issued an analyst report entitled "Quick Take: ENHANCE End Point Modified," stating:

> ***The number of images appears overwhelming and because [of] additional variability in some of the data, detected as part of the validation/data review procedures, ENHANCE is taking longer than expected to conclude. This variability can also confound the outcome.*** The narrowed single measurement should expedite the analysis and ***limit additional confounding variability. Despite the study remaining unblinded***, we are unsure whether this change has a statistical penalty, compromises the clinical utility of the data, and whether there is FDA buy-in to the change.

(Emphasis added). Similarly, on November 21, 2007, Bear Stearns issued an analyst report, acknowledging that, "[w]hile blinded data analysis is ongoing, an independent panel recommended focusing the primary endpoint to the common carotid artery to expedite the data processing . . . ."

II. The Company's Purported Risk Disclosures Were False and Misleading, and Insufficient to Insulate Defendants from Liability

290. Numerous Schering public filings prior to and during the Relevant Period included a "Risk Factors" section identifying "risks and uncertainties related to the Company's business" that "may" cause "[t]he Company's future operating results and cash flows [to] differ materially from the results" described in each public filing. Specifically, Schering's July 2006 Form 10-Q,

October 2006 Form 10-Q, 2006 Form 10-K filed February 2007, April 2007 Form 10-Q, July 2007 Form 10-Q, Form 8-K filed October 22, 2007, and October 2007 Form 10-Q, as well as the Registration Statement and the Common Stock and Preferred Stock Prospectuses, contain virtually identical disclosures or refer back to prior filings with nearly identical disclosures, that state:

> Schering-Plough's ability to generate profits and operating cash flow is largely dependent upon the continued profitability of Schering-Plough's cholesterol franchise, consisting of VYTORIN and ZETIA . . . ***As a result of Schering-Plough's dependence on key products, any events that adversely affect the markets for these products could have a significant impact on results of operations. These events include loss of patent protection, increased costs associated with manufacturing, OTC availability of Schering-Plough's product or a competitive product, the discovery of previously unknown side effects, increased competition from the introduction of new, more effective treatments and discontinuation or removal from the market of the product for any reason.*** . . . For example, the profitability of Schering-Plough's cholesterol franchise may be adversely affected by the introduction of multiple generic forms in December 2006 of two competing cholesterol products that lost patent protection earlier in the year.
>
> * * *
>
> Recently, clinical trials and post-marketing surveillance of certain marketed drugs of competitors' within the industry have raised safety concerns that have led to recalls, withdrawals or adverse labeling of marketed products. In addition, these situations have raised concerns among some prescribers and patients relating to the safety and efficacy of pharmaceutical products in general.
>
> * * *
>
> Schering-Plough operates in a highly competitive industry. Schering-Plough competes with a large number of multinational pharmaceutical companies, biotechnology companies and generic pharmaceutical companies. Many of Schering-Plough's competitors have been conducting research and development in areas both served by Schering-Plough's current products and by those products Schering-Plough is in the process of developing.

> ***Competitive developments that may impact Schering-Plough include technological advances by, patents granted to, and new products developed by competitors or new and existing generic, prescription and/or OTC products that compete with products of Schering-Plough or the Merck/Schering-Plough Cholesterol Partnership. In addition, it is possible that doctors, patients and providers may favor those products offered by competitors due to safety, efficacy, pricing or reimbursement characteristics, and as a result Schering-Plough will be unable to maintain its sales for such products.***

(Emphasis added).

291. For the same reasons discussed in ¶ 270 above, in light of the ENHANCE results, these purported risk disclosures were materially misstated and omitted to state material facts required therein or necessary to make the statements contained therein not misleading, at all times throughout the Relevant Period. In addition, these purported risk disclosures identified concerns over the efficacy of the cholesterol franchise as a possible risk to Schering's business, when the ENHANCE results in fact called into question the efficacy of those drugs at the time these disclosures were made, thereby rendering the disclosures materially false and misleading.

292. Given the specific, adverse facts that existed at the time the Company issued each of these purported risk disclosures, the generalized risks they identified (including Schering's dependence on the continued profitability of Zetia and Vytorin and the risks posed by, among other things, increased competition based on competing drugs' efficacy and pricing) were not sufficiently particularized to insulate Defendants from liability for the material omission from these documents of ENHANCE's failure.

THE TRUTH BEGINS TO EMERGE

I. The December 2007 Letter from Congressmen Dingell and Stupak

293. On December 11, 2007, Congressmen Dingell and Stupak sent the First House Letter to Defendant Hassan (as well as Richard Clark, Chairman and CEO of Merck) to advise that, pursuant to Rules X and XI of the Rules of the U.S. House of Representatives, the Committee on Energy and Commerce and the House Oversight Subcommittee "are investigating the withholding of clinical trial data that may significantly affect the medical management of hypercholesterolemia." In relevant part, the First House Letter stated as follows:

> [W]e are interested in Schering-Plough and Merck's delay in making complete data available from the [ENHANCE] trial. . . . ***The ENHANCE trial was completed in April 2006, and yet no data from the trial have been published or presented in their entirety. In fact, it appears that the study itself was not registered with ClinicalTrials.gov until October 31, 2007, a full 18 months after completion of the study. In addition, the endpoint indicated in the ClinicalTrials.gov web site appears to differ from the endpoint described in the initial study design.***
>
> Recent news reports indicate that ENHANCE data may be presented at the American College of Cardiology Conference in March 2008, but only after using partial results and after changing the trial's primary endpoint. According to Schering-Plough's spokesman Lee Davies, a panel of outside scientists recommended changing the trial's primary endpoint. ***We are concerned with the delay in releasing the results of the study, the timing of ENHANCE trial registration, and the apparent manipulation of trial data.***

(Emphasis added). In addition, Congressmen Stupak and Dingell requested that the Company and Merck make available the ENHANCE study director (Dr. Enrico Veltri), the Principal Investigator (Dr. Kastelein), and corporate officials for interviews, and to provide Congress with various documents and memoranda regarding ENHANCE.

294. On December 12, 2007, Reuters published an article, entitled "Merck, Schering-Plough cholesterol trial faces probe," which revealed for the first time that U.S. lawmakers were investigating Schering and Merck "on allegations that the drugmakers are withholding data from a study that may change how doctors treat high cholesterol." The article noted that "[c]ardiologists have been clamoring for full results from the ENHANCE trial, which involved some of the industry's best-selling cholesterol-lowering drugs." In response to this disclosure, the Company's stock price dropped from a closing price of $29.00 on December 11, 2007, to close at $27.94 on December 12, 2007.

295. Also on December 12, 2007, Cowen and Company issued an analyst report, entitled "Quick Take: ENHANCE Congressional Hearing News Today But Not Likely to Linger." In this report, the analyst remained optimistic that any weakness in Schering's stock price due to ENHANCE presented a "buying opportunity," stating the following:

> ***[ENHANCE] has taken longer than SGP and MRK had originally anticipated because, during the analysis, observations of variability in some of the data were detected as part of the validation/data review procedures.*** In addition we believe this study to have a high efficacy hurdle due to an active control, the familial hypercholesterolemia population, the previous exposure to statins, and plaque regression end point. As of November 19 both companies were committed to a presentation of some of the data at ACC in March 2008. ***We believe any weakness in SGP due to this news is a buying opportunity.***

(Emphasis added).

II. The January 2008 Morgan Stanley Conference

296. On January 3, 2008, Defendant Hassan presented at Morgan Stanley's Pharmaceutical CEOs Unplugged Conference. During the scripted portion of his presentation, Defendant Hassan briefly discussed the timing of ENHANCE, as follows:

> Most of you are also aware of a ***small surrogate endpoint trial*** called the ENHANCE trial and, at this time, we are looking at the ENHANCE trial. At the time it was initiated, it had a lot of scientific interest. ***The study methodology of this trial has been challenging. And there have also been challenges to the variability in the reading of the ultrasound images in this trial.***

(Emphasis added).

297. During the Q&A portion of Hassan's presentation, analysts asked numerous pointed questions regarding ENHANCE, and specifically raised concerns that the results of the study might hurt Schering's cholesterol franchise. Rather than directly address such concerns, Hassan falsely and misleadingly claimed, instead, that the results of the trial would only be relevant to a small group of potential consumers. For example:

> **[Analyst - Morgan Stanley]**: "[I]f the trial results are not favorable, if VYTORIN does not show superiority over simva 80, which seems to be a good possibility given the challenges in this study population, how do you protect your franchise?"
>
> **Defendant Hassan**: "The lower LDL is better is a very strong proposition and a very well accepted proposition. . . . ***This is very, very strong clinical evidence based on many, many trials including non statins, statins all kinds of products. So that is the underlying strength behind ZETIA and VYTORIN.***
>
> ***As far as [ENHANCE] is concerned, the market for these patients is not the mainstream market for VYTORIN; we will certainly look at that situation.*** But it's a surrogate endpoint trial that relies on ultrasound imaging. It's not an easy area to work with."
>
> * * *
>
> **[Analyst - Searock Capital Management]**: "Is there a scenario where you would envision potentially sales trends to go against you from what we've seen in the past? In other words, the doc[tors] we've spoken with, it seems to me that the expectation is that it shouldn't do much. I'm just curious, ***if something were to arise out of this data, what would it be, do you think, and is there***

> ***any scenario in which you could envision those [prescription] trends changing?"***
>
> * * *
>
> **Defendant Hassan**: "ENHANCE . . . is not a large trial, in a very, very special population with very, very high doses, the highest doses – these are not the mainstream doses. ***I don't know why this would have any impact on mainstream use. It's not the same population and it's not the same dosage.*** And also the reading of this is not LDL which is the gold standard, this is some other approach which is hard to accomplish. ***So from everything I'm seeing this is one of many, many trials and it will advance the scientific knowledge but it's a small trial."***

(Emphasis added).

III. The January 2008 Press Releases and News Stories

298. On January 14, 2008, Schering and M/SP issued a press release, entitled "Merck/Schering-Plough Pharmaceuticals Provides Results of the ENHANCE Trial," announcing long-awaited partial results of ENHANCE. Remarkably, the study found that "***[t]here was no statistically significant difference between treatment groups on the primary endpoint. . . . [and that] secondary imaging endpoints showed no statistical difference between treatment groups."*** (Emphasis added). In addition, the study showed that patients taking Vytorin actually suffered from ***more*** adverse events than the patients who were on Zocor. As noted above, in response to these disclosures, the Company's common stock price declined approximately 8% from a closing price of $27.73 per share on Friday, January 11, 2008, to close at $25.52 per share on Monday, January 14, 2008. Similarly, the price of Schering preferred stock declined 5.64% from a closing price of $249.50 per share on January 11, to close at $235.42 per share on January 14.

299. Later that day, in an article entitled "Schering, Merck cholesterol drug misses goal," Reuters attributed the Company's rapidly declining share price to its disclosures regarding ENHANCE, stating, in relevant part, that:

> Merck & Co . . . and Schering-Plough Corp . . . said on Monday their shared Vytorin cholesterol treatment failed to significantly halt clogging of arteries better than an older generic drug.
>
> ***Schering-Plough, which depends more on the widely used Vytorin, fell more than 6 percent . . . .***
>
> Vytorin's failure to prove greater effectiveness in this measure over Zocor – which is available in cheaper generic forms – could hurt its standing in the hotly competitive market for cholesterol treatments.
>
> ***"In an era where there are cost-control pressures, if you can't prove better efficacy, the value proposition gets questioned,"*** Miller Tabak analyst Les Funtleyder said.
>
> ***The closely-watched trial examined Vytorin*** – which combines the companies' Zetia drug with Merck's older Zocor drug – against Zocor alone in demonstrating plaque regression and cholesterol lowering. Patients in both groups received a high dose of Zocor.
>
> * * *
>
> ***The trial has garnered intense investor interest because Vytorin and Zetia have annual sales of about $5 billion, and are important to future earnings growth of the companies.***
>
> The results could make it tougher for the companies to make the case for spending more on Vytorin over generic cholesterol drugs, Edward Jones analyst Linda Bannister said.
>
> ***"People are concerned about near-term prescription growth for Zetia and Vytorin,"*** Bannister said. "People will wonder if (they are) getting any bang for the buck here."

(Emphasis added).

300. On January 15, 2008, the Company's stock price continued to decline as more reports about the safety and efficacy of Vytorin were disclosed to the market. For example, the Associated Press reported on January 15 that:

> **Study: Cholesterol Combination Drug Vytorin Not Superior to Solo Drug**
>
> NEWARK, N.J. (AP) -- ***A clinical trial has shown that the combination cholesterol drug Vytorin is no more effective than a high dose of one of its components available generically, Vytorin's makers said Monday.***
>
> Vytorin, developed by Merck & Co. and Schering-Plough Corp., is a combination of Zetia and Merck's Zocor, which lost patent protection in 2006. Amid concerns about whether Vytorin posed a risk of liver damage, Wall Street has been anxiously awaiting details on results of the study begun in 2002.
>
> In the quarter ended Sept. 30, sales of Zetia and Vytorin hit $1.3 billion, up 26 percent from the year-ago period.
>
> * * *
>
> The study measured the amount of artery-clogging plaque in three areas. It focused on a group of 720 patients with a rare condition predisposing them to high cholesterol. The patients were given either Vytorin or a high dose of generic Zocor, known as simvastatin.
>
> In December, a congressional committee requested more information on the study. The results were delayed, the companies maintained, because of the complexity of the data.

(Emphasis added).

301. Further, in a January 15 article, entitled "Schering-Plough sell off worsens on Vytorin concerns," Reuters reported, in relevant part, that:

> ***Shares of Schering-Plough Corp . . . fell a second consecutive day on Tuesday on fears that a failed clinical trial could dampen demand for the company's blockbuster Vytorin cholesterol drug, analysts and money managers said. Schering-Plough's stock fell***

> ***$1.74, or 6.8 percent, to $23.78 on the heels of a 7.9 percent decline on Monday.***
>
> The company and partner Merck & Co . . . said on Monday their shared Vytorin failed to halt clogging of arteries better than Merck's older Zocor, which is now sold in inexpensive generic forms.
>
> In fact, slightly more plaque built up in the carotid arteries of patients taking Vytorin during the two-year so-called Enhance trial than those taking Zocor, spurring some doctors to question the benefit of costly Vytorin.
>
> "Vytorin accounts for two-thirds of Schering-Plough's profits, which is why the (stock) market has been so skittish the last two days," said Tom Goetzinger, senior securities analyst with Dreman Value Management LLC.
>
> Goetzinger said earlier assumptions that patients needing a cholesterol fighter for the first time would opt for potent Vytorin, had helped fuel expectations that Schering-Plough profits would grow 24 percent this year and another 17 percent in 2009.
>
> ***"The market is now saying we're not so confident about those potential new users," he said, and is fretting that insurers and pharmacy benefit managers could steer first-time patients to rival medicines.***
>
> "They will be able to argue, 'We're not getting enough benefit to justify the cost'" of Vytorin, Goetzinger said.
>
> Credit Suisse analyst Catherine Arnold said on Tuesday AstraZeneca Plc's . . . Crestor and Pfizer Inc's . . . Lipitor could benefit in the short term from the new doubts about Vytorin.
>
> But Arnold predicted that those doubts would recede after full results of the Enhance trial are presented at medical meeting in March and that Vytorin market share gains will resume by year-end.

(Emphasis added).

302. In response to the growing concerns discussed in these (and other) news articles published on January 15, the Company's stock price suffered a single-day decline of 6.8%,

falling from a closing price of $25.52 per share on January 14, 2008, to close at $23.78 per share on January 15, 2008.

303. After the market close on January 16, 2008, The Wall Street Journal reported that Congress was investigating advertising for Vytorin, suspecting that the Company knew the results of ENHANCE yet continued to suggest that Vytorin had an advantage over generic statins. In addition, the law firm Hagens Berman Sobel Shapiro announced that it was investigating the marketing for Vytorin and Zetia. On the next day, January 17, 2008, Schering common stock fell another 7.96%.

304. On January 22, after the close of the market, the Associated Press published an article, entitled "Firm: Vytorin prescriptions fall after questions on effectiveness," which revealed that questions surrounding ENHANCE prompted Defendant M/SP to suspend temporarily its television ads for Vytorin:

> ***Prescriptions for embattled cholesterol drug Vytorin fell almost 10 percent last week after a study raised questions about its effectiveness, a market-research firm said Tuesday.*** Total U.S. prescriptions for Merck & Co.'s and Schering-Plough's Vytorin in the week ended Jan. 18 fell about 9.5 percent compared to the previous week, drug-data vendor Verispan said in an estimate provided to *Dow Jones* Newswires.
>
> Results of the so-called "Enhance" patient trial were released Jan. 14, and showed that Vytorin was no better than generic simvastatin in slowing artery-clogging despite reducing bad cholesterol to a greater degree. Vytorin is a single-tablet combination of simvastatin and Zetia.
>
> ***Skip Irvine, a spokesman for the Merck/Schering-Plough partnership, declined to comment on the prescription data. However, Irvine confirmed that the joint venture has temporarily suspended TV ads for Vytorin*** due to what he called the "misinterpretation" of the Enhance study. The study prompted some doctors to call for limiting the use of Vytorin and Zetia, at

> least until ongoing patient studies show whether it can reduce the risk for heart attacks and other cardiovascular results.

(Emphasis added).

305. In a second article, also published on January 22, 2008 after the close of the market, the Associated Press reported that "Banc of America Securities analyst Chris Schott reduced his Vytorin forecasts by $200 million to $400 million per year between 2008 and 2012 . . . ." On January 23, the next day of trading, Schering's common stock price declined nearly 4%, from a closing price of $20.36 per share on January 22, 2008, to close at $19.59 per share on January 23, 2008.

306. On January 25, 2008, the FDA disclosed that it was conducting a review into whether it should take regulatory action against Schering and Merck for their handling of ENHANCE. Following this disclosure, Schering's common stock price fell from $20.17 per share on January 24, 2008, to $19.02 per share on January 25, 2008, marking a single-day decline of 5.7%.

IV. The March 2008 ENHANCE Presentation

307. The full and detailed ENHANCE results were finally disclosed on March 30, 2008 at the Chicago ACC Conference. Following the presentation of the study, a four-doctor expert panel issued its recommendation on the use of Vytorin in light of the results. As noted above, Dr. Krumholz of Yale spoke on behalf of the panel, stating that Vytorin's clinical benefit was dubious and that the drug should therefore be used as a ***last resort***. His prepared remarks included the following:

> ***Critics may opine about reasons for the findings, including the possibility the measures were not precise enough or the population was not typical. But the most likely explanation is that the compound did not work.*** It lowered LDL but did not

> retard the progression of atherosclerosis as we saw in prior studies where the use of statin therapy or intensive statin therapy had this effect. Now this is still just one study of ezetimibe and one that employed measurements of arteries and not clinical endpoints, but ***this study provides no new evidence to support the use of the drug. And it moves us to more uncertainty about the benefit of the drug***.
>
> * * *
>
> So where does this leave us? ***ENHANCE is an important negative study that provides no new support for a widely prescribed drug and whose surprising findings remind us how little we know about the overall risks and benefits of this drug – whether there is really a net clinical benefit to its lipid-lowering effect.***
>
> ***For clinicians who may have employed this medication before exhausting options with statins, the strongest recommendation here is to turn back to statins, especially those with favorable outcomes data. Go back to what we know works. Let us stay with the evidence. Patients who need medication to treat cholesterol should be maximized on statin therapy – and different statins may need to be tried before a patient is considered to have failed statin therapy.***
>
> Then, the next options should be medications that have been shown to be associated with better clinical outcomes – niacin, fibrates and resins. We know that they are not tolerated as well, but they have evidence and are worth trying.
>
> ***And then for those who have failed these therapies, and this should be a relative small group, the question of whether we should use ezetimibe will likely be unresolved until the outcomes studies are available.*** Until then we will not know the net effect of this drug on patients, and whether the reduction of LDL with this drug produces a clinical meaningful effect.

(Emphasis added).

308. The NEJM also weighed in on March 30, 2008, publishing an editorial on its website that addressed the ENHANCE results (later published in the April 3, 2008 volume). Like the expert panel, the editorial recommended prescribing Vytorin only as a ***last resort***:

> Until [outcome] data are available, it seems prudent to encourage patients whose LDL cholesterol levels remain elevated despite treatment with an optimal dose of a statin to redouble their efforts at dietary control and regular exercise. ***Niacin, fibrates, and resins should be considered when diet, exercise, and a statin have failed to achieve the target, with ezetimibe reserved for patients who cannot tolerate these agents.***

(Emphasis added).

309. As noted above, on March 31, 2008, the first day of trading following the March 30 presentation of the ENHANCE results, Schering's stock price dropped from a closing price of$19.47 on Friday, March 28, 2008, to a close of $14.41 on Monday, March 31, 2008, a decline of 26%, on extremely heavy trading volume of over 167 million shares traded. The price of Schering preferred stock also dropped from a closing price of $192.78 on Friday, March 28, to a close of $153.18, a one-day decline of 20.54%, on heavy trading volume.

LOSS CAUSATION

310. During the Relevant Period, as detailed herein, Defendants engaged in a course of conduct that artificially inflated the price of Schering securities. As a result, Plaintiffs purchased Schering securities at artificially-inflated prices and were damaged when the artificial inflation gradually dissipated when a series of corrective disclosures entered the market concerning ENHANCE.

311. On December 11, 2007, Congressmen Dingell and Stupak sent the First House Letter to Defendant Hassan to inform him that the Committee on Energy and Commerce and the House Oversight Subcommittee "are investigating the withholding of clinical trial data that may significantly affect the medical management of hypercholesterolemia." As discussed above, the First House Letter requested that the Company make available certain corporate officials for

interviews, and to provide the Subcommittee with various documents and memoranda regarding ENHANCE. This news was not disseminated to the market by the close of trading. The Company's stock price closed at $29.00 per share on volume of 12,367,100 shares, consistent with Schering's average volume of roughly 10.7 million shares during the thirty prior trading days.

312. On December 12, 2007, Reuters published an article, entitled "Merck, Schering-Plough cholesterol trial faces probe," which revealed for the first time that U.S. lawmakers were investigating Schering and Merck "on allegations that the drugmakers are withholding data froma study that may change how doctors treat high cholesterol." The article also noted that "[c]ardiologists have been clamoring for full results from the ENHANCE trial, which involved some of the industry's best-selling cholesterol-lowering drugs." In response to this disclosure, the Company's stock price dropped from a closing price of $29.00 on December 11, 2007, to close at $27.94 on December 12, 2007, on volume of 43,401,700, more than four times Schering's average volume during the thirty prior trading days.

313. On January 14, 2008, the Company and M/SP issued a press release entitled "Merck/Schering-Plough Pharmaceuticals Provides Results of the ENHANCE Trial," announcing long-awaited partial results of ENHANCE. As discussed above, the study concluded that "[t]here was no statistically significant difference between treatment groups on the primary endpoint . . . [and that] secondary imaging endpoints showed no statistical difference between treatment groups." In addition, ENHANCE showed that patients taking Vytorin actually suffered from ***more*** adverse events than the patients who were on Zocor. Following the January 14 disclosure, the Company's common stock price dropped by approximately 8% from a closing

price of $27.73 per share on January 11, 2008, to close at $25.52 per share on January 14, 2008, on volume of 40,851,849 shares, nearly three times Schering's average volume during the thirty prior trading days. This disclosure, alone, wiped out more than $3.5 billion in market capitalization. Similarly, the price of Schering preferred stock declined 5.64% from a closing price of $249.50 per share on January 11, to close at $235.42 per share on January 14.

314. On January 15, 2008, news continued to leak into the market concerning the implications that ENHANCE would have on the Company's demand and profitability. For example, as discussed above, Reuters reported that: "Shares of Schering-Plough Corp. . . . fell a second consecutive day on . . . fears that a failed clinical trial could dampen demand for the company's blockbuster Vytorin cholesterol drug." In response, Schering's common stock price dropped from a closing price of $25.52 on January 14, 2008, to close at $23.78 on January 15, 2008, marking a single-day decline of 6.82% on heavy volume.

315. As discussed above, after the market close on January 16, 2008, The Wall Street Journal reported that Congress was investigating advertising for Vytorin, and a law firm announced that it was investigating the marketing for Vytorin and Zetia. On the next day, January 17, 2008, Schering common stock fell another 7.96%.

316. On January 22, 2008, after the close of the market, the Associated Press reported that M/SP temporarily suspended its television ads for Vytorin. As discussed above, the Associated Press also reported that, since January 14, prescriptions for Vytorin had dropped by almost 10 percent. On January 23, the next day of trading, the Company's stock price declined from a closing price of $20.36 per share on January 22, 2008, to $19.59 per share on January 23, 2008, on heavy trading volume.

317. On January 25, 2008, the FDA disclosed in a press release that it was conducting an ongoing review of whether it should take regulatory action over Schering and Merck's handling of ENHANCE. In response, the Company's common stock price fell by 5.7% from a closing price of $20.17 per share on January 24, 2008, to a closing price of $19.02 per share on January 25, 2008, on volume of 83,867,190 shares, nearly 3.5 times Schering's average volume during the thirty prior trading days.

318. In sum, as news leaked into the market concerning the truth about ENHANCE, the Company's stock price fell by more than 34%, causing a loss of more than ***$16 billion*** in market capitalization, between the close of the market on December 11, 2007 and the close of the market on January 25, 2008.

319. On Sunday, March 30, 2008, the full and detailed results of ENHANCE were revealed at the Chicago ACC Conference. Following the presentation of the study, a four-doctor expert panel issued its recommendation on the use of Vytorin in light of the results. As discussed above, Dr. Krumholz, who spoke on behalf of the panel, stated that their "strongest recommendation here is to turn back to statins, especially those with favorable outcomes data." In addition, Dr. Krumholz explained that "the most likely explanation [for ENHANCE's results] is that the compound did not work," and stressed that "this study provides no new evidence to support the use of the drug." On March 31, 2008, the first day of trading following the March 30 presentation, the Company's common stock price dropped nearly 26% from a closing price of $19.47 on Friday, March 28, 2008, to close at $14.41 per share on Monday, March 31, 2008 on volume of over 167 million shares traded, more than ***11.6 times the average volume*** during the thirty prior trading days, causing a loss of more than ***$8.2 billion*** in market capitalization. The

price of Schering preferred stock also dropped from a closing price of $192.78 on Friday, March 28, to a close of $153.18, a one-day decline of 20.54%, on heavy trading volume of 717,158 shares traded, approximately 10.8 times the average volume during the thirty prior trading days, causing a loss of more than ***$396 million*** in market capitalization.

320. In sum, as investors learned the truth about the ENHANCE study between December 11, 2007 and March 31, 2008, the Company's common stock price fell more than ***52%***, wiping out more than ***$23.63 billion*** in market capitalization, and the Company's preferred stock price similarly fell more than ***40%*** during that time period, wiping out ***$1.039 billion*** in market capitalization.

321. Each of the declines in the Company's stock price described above were significant after taking into account changes on the same days in the overall stock market and in relevant indices. Further, as set forth above, each of these stock price declines was caused by the disclosure of previously concealed information relating to the material misstatements and omissions alleged herein.

322. Had Plaintiffs known of the material adverse information alleged herein, they would not have purchased Schering securities at artificially inflated prices and they would not have proximately suffered losses as the previously-withheld information became revealed to the market.

NO SAFE HARBOR

323. The statutory safe harbor applicable to forward-looking statements under certain circumstances does not apply to any of the false and misleading statements pled in this Complaint. None of the misstatements and omissions complained of herein were forward-

looking statements, nor were any of the statements identified as forward-looking when made. Rather, the false or misleading statements and omissions complained of in this Complaint concerned omissions of historical and/or current facts and conditions existing at the time the statements were made.

324. Alternatively, to the extent that any of the false or misleading statements alleged herein can be construed as forward-looking statements, they were not accompanied by any meaningful cautionary language identifying important facts that could cause actual results to differ materially from those in the purportedly forward-looking statements. Schering provided only general disclosures that were not meaningful in light of the ENHANCE results they omitted to disclose. Alternatively, to the extent the statutory safe harbor would otherwise apply to any forward-looking statements pleaded herein, Defendants are liable for those false or misleading forward-looking statements because at the time those statements were made, the speaker(s) knew the statement was false or misleading, or the statement was authorized and/or approved by an executive officer of Schering who knew that the statement was materially false or misleading when made.

PRESUMPTION OF RELIANCE

325. Plaintiffs are entitled to a presumption of reliance under *Affiliated Ute Citizens of Utah v. U.S.*, 406 U.S. 128 (1972), because the claims asserted herein against Defendants are predicated in part upon material omissions of fact that Defendants had a duty to disclose.

326. In the alternative, Plaintiffs are entitled to a presumption of reliance on Defendants' material misrepresentations and omissions pursuant to the fraud-on-the-market doctrine because,

at all relevant times, the market for Schering securities was open, efficient, and well-developed for the following reasons, among others:

- The market for Schering securities was, at all relevant times, an efficient market that promptly digested current information with respect to the Company from all reliable, publicly-available sources and reflected such information in the price of Schering securities;

- Schering common stock met the requirements for listing and was listed and actively traded on the NYSE, a highly efficient and automated market;

- The Company was consistently followed, before and throughout the Relevant Period, by the media, which issued over 500 news stories regarding Schering during that time. Schering was followed by numerous securities analysts employed by firms including: Citigroup, Inc.; Deutsche Bank Securities, Inc.; JP Morgan Research; Merrill Lynch; UBS Research; Bear Stearns & Co., Inc.; Datamonitor Company Profiles; SG Cowen Securities Corp.; Life Science Analytics; Morgan Stanley; Corporate Technology Information Services, Inc.; Thomson StreetEvents; and Prudential Equity Group, Inc., among others, who wrote reports about the Company and the value of its securities that were publicly available and entered the public marketplace. Indeed, there was extensive securities analyst coverage of Schering, with over 200 analyst reports published prior to and during the Relevant Period;

- The price of Schering securities reacted promptly to the dissemination of new information regarding the Company, as set forth above. Schering securities were actively traded throughout the Relevant Period, with substantial trading volume and average weekly turnover and high institutional investor participation. The average daily trading volume for Schering common stock during the period from July 24, 2006 to March 28, 2008 was 11,357,952 shares and the average weekly turnover was 4.62%;

- Schering regularly communicated with public investors through established market communication mechanisms, including through regular press releases, which were carried by national and international news wires, and through other wide ranging public disclosures, such as communications and conferences with investors, the financial press and other similar reporting services;

- As a public company, Schering filed period public reports with the SEC;

- Schering met the SEC's requirements to register debt and equity securities filed on Form S-3 and, in fact, filed a Form S-3ASR in connection with the Offering, among other SEC filings; and

- Schering's securities were rated by rating agencies such as Moody's, Standard & Poor's, and Fitch Ratings.

327. As a result of the foregoing, the market for Schering securities promptly digested current information regarding Schering from all reliable, publicly available sources and reflected such information in the price of Schering's securities. Under these circumstances, Plaintiffs, as purchasers of Schering securities during the Relevant Period, suffered injury through their purchases of Schering securities at artificially-inflated prices and a presumption of reliance applies.

328. Accordingly, Plaintiffs did rely and were entitled to have relied on the integrity of the market price for Schering securities and to a presumption of reliance on Defendants' materially false and misleading statements and omissions during the Relevant Period. Additionally, Plaintiffs are entitled to a presumption of reliance because the claims asserted herein against Defendants are also predicated upon omissions of material fact which there was a duty to disclose.

DIRECT RELIANCE

329. Plaintiffs and/or their investment managers acting on their behalf, actually, reasonably, and/or justifiably relied upon Defendants' misleading statements by, *inter alia*: (1) reading Schering's SEC filings, including without limitation, annual reports filed on Form 10-K and quarterly reports filed on Form 10-Q; (2) reading analyst reports regarding Schering; (3) reading newspaper and other media accounts regarding Schering; and (4) listening to, or reading the transcripts of, earnings conference calls, and other investor presentations by Schering management.

330. In reliance on Defendants' misleading statements and/or omissions, Plaintiffs purchased Schering securities after each of the misleading statements alleged herein during the Relevant Period, as reflected in the trade data attached hereto as Exhibits A, B, and C.

COUNT ONE

VIOLATION OF SECTION 10(b) OF THE EXCHANGE ACT AND RULE 10b-5 PROMULGATED THEREUNDER AGAINST ALL DEFENDANTS

331. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

332. During the Relevant Period, Defendants carried out a plan, scheme, and course of conduct which was intended to and, throughout the Relevant Period, did: (i) deceive the investing public regarding Schering's business, operations, management, and the intrinsic value of Schering securities; (ii) enable Defendants to artificially inflate the price of Schering securities; (iii) enable Cox, a Schering insider, to sell over $28 million of her privately-held Schering shares and allow the Company itself to register and sell over $4.08 billion in common and preferred stock during the Relevant Period and while in possession of material, adverse, non-public information about the Company; and (iv) cause Plaintiffs to purchase Schering securities at artificially-inflated prices. In furtherance of this unlawful scheme, plan, and course of conduct, Defendants jointly and individually (and each of them) took the actions set forth herein.

333. Defendants: (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon purchasers of the Company's securities in an effort to maintain artificially

high market prices for Schering's securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5. All of the Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

334. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about the business, operations and future prospects of Schering as specified herein.

335. Defendants employed devices, schemes, and artifices to defraud, while in possession of material, adverse, non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Schering's value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and omitting to state material facts necessary in order to make the statements made about Schering and its business operations and future prospects in the light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices, and a course of business which operated as a fraud and deceit upon the purchasers of Schering securities during the Relevant Period.

336. Defendant Schering is liable for all materially false and misleading statements made prior to and during the Relevant Period, as alleged above, including the false and misleading statements in:

- Schering's Form 8-K and press release of July 24, 2006;
- Schering's Form 10-Q, filed with the SEC on July 28, 2006;
- Schering's Form 8-K and press release of October 20, 2006;

- Schering's Form 10-Q, filed with the SEC on October 27, 2006;
- Schering's Form 8-K and press release of January 29, 2007;
- Schering's Form 10-K, filed with the SEC on February 28, 2007;
- Schering's Form 8-K and press release of April 19, 2007;
- Schering's Form 10-Q, filed with the SEC on April 27, 2007;
- Schering's Form 8-K and press release of July 23, 2007;
- Schering's Form 10-Q, filed with the SEC on July 27, 2007;
- Schering's Form 8-K and press release of October 22, 2007;
- Schering's Form 10-Q, filed with the SEC on October 26, 2007;
- M/SP's press release of November 19, 2007.

337. Schering is also liable for the false and misleading statements made in the Registration Statement filed with the SEC on Form S-3ASR on August 2, 2007 and in the Common Stock and Preferred Stock Prospectuses filed with the SEC.

338. Schering is further liable for the false and misleading statements made by Schering officers in press releases and during conference calls and at conferences with investors and analysts, as alleged above, as the makers of such statements and under the principle of respondeat superior.

339. Defendant M/SP is liable for materially false and misleading statements made prior to and during the Relevant Period, as alleged above, including the false and misleading statements in M/SP's press release of November 19, 2007.

340. Defendants Hassan and Cox, as top executive officers of the Company, are liable as direct participants in the wrongs complained of herein. Through their positions of control and authority as officers of the Company, Hassan and Cox were able to and did control the content of

the public statements disseminated by Schering. These Defendants had direct involvement in the daily business of the Company and participated in the preparation and dissemination of Schering's false and misleading statements as set forth above.

341. In addition, Defendants Hassan and Cox are liable for, among other material omissions and false and misleading statements, the false and misleading statements they made and/or signed as follows:

Defendant Hassan

> Defendant Hassan signed the Form 10-K for the year ended December 31, 2006; the Registration Statement filed with the SEC on Form S-3ASR on August 2, 2007; and certifications in the Forms 10-K and 10-Q filed with the SEC on July 28, 2006; October 27, 2006; February 28, 2007; April 27, 2007; July 27, 2007; and October 26, 2007.
>
> Defendant Hassan made statements during numerous conference calls prior to and during the Relevant Period, including earnings calls on July 24, 2006; October 20, 2006; January 29, 2007; April 19, 2007; July 23, 2007; and October 22, 2007.
>
> Defendant Hassan made statements in and was directly responsible for other statements made in Schering press releases filed with the SEC as attachments to Forms 8-K, including forms filed on the following dates: July 24, 2006; October 20, 2006; January 29, 2007; April 19, 2007; July 23, 2007; and October 22, 2007.

Defendant Cox

> Defendant Cox made statements during numerous conference calls prior to and during the Relevant Period, including earnings calls on July 24, 2006; October 20, 2006; January 29, 2007; April 19, 2007; July 23, 2007; and October 22, 2007.

342. The allegations above establish a strong inference that Defendants acted with scienter throughout the Relevant Period in that they had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth in that

they failed to ascertain and to disclose such facts. Such Defendants' material misrepresentations and/or omissions were done knowingly or with recklessness for the purpose and effect of concealing Schering's operating condition and future business prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' material misstatements and omissions prior to and throughout the Relevant Period, if they did not have actual knowledge of the misrepresentations and omissions alleged, Defendants were reckless in failing to obtain such knowledge by recklessly refraining from taking those steps necessary to discover whether those statements were false or misleading.

343. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market price of Schering securities was artificially inflated during the Relevant Period. In ignorance of the fact that market prices of Schering's publicly-traded securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trade, and/or on the absence of material adverse information that was known to or recklessly disregarded by Defendants but not disclosed in public statements by them during the Relevant Period, Plaintiffs acquired Schering securities during the Relevant Period at artificially high prices and were damaged thereby.

344. At the time of said misrepresentations and omissions, Plaintiffs were ignorant of their falsity, and Defendants' material omissions. Had Plaintiffs and the marketplace known the truth, Plaintiffs would not have purchased or otherwise acquired their Schering securities, or, if they had acquired such securities during the Relevant Period, they would not have done so at the artificially inflated prices which they paid.

345. By virtue of the foregoing, Defendants have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

346. As a direct and proximate result of their wrongful conduct, Plaintiffs suffered damages in connection with their respective purchases and sales of the Company's securities during the Relevant Period.

COUNT TWO

VIOLATION OF SECTION 20(a) OF THE EXCHANGE ACT AGAINST DEFENDANTS HASSAN AND COX

347. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

348. Defendants Hassan and Cox acted as controlling persons of Schering within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions, and their ownership and contractual rights, participation in, and/or awareness of the Company's operations and/or intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, Hassan and Cox had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiffs contend are false and misleading. Hassan and Cox were provided with or had unlimited access to copies of the Company's reports, press releases, public filings, and other statements alleged by Plaintiffs to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

349. In particular, Hassan and Cox had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, are presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

350. As set forth above, Hassan and Cox each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their positions as controlling persons, Hassan and Cox are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Hassan's and Cox's wrongful conduct, Plaintiffs suffered damages in connection with their purchases of the Company's securities during the Relevant Period.

COUNT THREE

VIOLATION OF SECTION 20A OF THE EXCHANGE ACT BY PLAINTIFFS LOCAL 1500 AND COLONIAL FIRST AGAINST DEFENDANTS COX AND SCHERING

351. Local 1500 and Colonial First repeat and reallege each and every allegation contained above as if fully set forth herein.

352. This claim is asserted by Local 1500 and Colonial First pursuant to Section 20A of the Exchange Act against Defendants Cox and Schering based on Local 1500's and Colonial First's purchases of shares of Schering common stock contemporaneously with Defendant Cox's sale of Schering common stock while she was in possession of material, non-public, adverse information that artificially inflated the value of those Schering shares.

353. Defendants Cox and Schering violated Sections 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder for the reasons stated in Count One, including Cox's violation of Section 10(b) and Rule 10b-5 for exercising her stock options and selling a total of 900,000

shares of Schering common stock on April 20, 2007 and May 1, 2007, while in possession of material, non-public, adverse information concerning ENHANCE's failure to demonstrate cardiovascular benefits of ezetimibe. Defendant Cox also violated Section 20(a) of the Exchange Act for the reasons stated in Count Two.

354. Contemporaneously with Defendant Cox's April 20, 2007 and May 1, 2007 insider sales of Schering common stock, Local 1500 purchased shares of common stock on a national securities exchange, on the following dates and in the following amounts

- April 13, 2007: 700 shares
- May 1, 2007: 1,500 shares
- May 9, 2007: 1,400 shares

355. Contemporaneously with Defendant Cox's April 20, 2007 and May 1, 2007 insider sales of Schering common stock, Colonial First purchased shares of common stock on a national securities exchange, on the following dates and in the following amounts:

- April 19, 2007: 13,700 shares
- April 20, 2007: 10,200 shares
- April 23, 2007: 3,300 shares
- April 24, 2007: 3,000 shares
- April 25, 2007: 4,300 shares
- April 26, 2007: 4,700 shares
- April 27, 2007: 5,500 shares

356. Defendant Schering, acting through its officers and agents, is liable pursuant to Section 20A(a) and 20A(c) of the Exchange Act for communicating material, non-public, adverse

information to Defendant Cox, thereby enabling her to trade on such information and damaging Local 1500 and Colonial First.

357. Local 1500 and Colonial First have been damaged as a result of the violations of the Exchange Act alleged herein.

358. By reason of their violations of the Exchange Act alleged herein, Defendants Cox and Schering are jointly and severally liable pursuant to Exchange Act Section 20A to Local 1500 and Colonial First, who purchased shares of Schering common stock contemporaneously with Defendant Cox's April 20, 2007 and May 1, 2007 sales of Schering common stock, for the communication and resulting transactions based on material, non-public, adverse information regarding Schering.

359. As a direct and proximate result of Defendants Cox's and Schering's wrongful conduct, Local 1500 and Colonial First seek disgorgement of Defendant Cox's profits (or losses avoided) from her transactions in Schering securities on April 20, 2007 and May 1, 2007.

COUNT FOUR

COMMON LAW FRAUD
AGAINST ALL DEFENDANTS

360. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

361. Defendants made the foregoing false and/or misleading statements, which were material, and/or failed to disclose or concealed information necessary to make such statements not misleading, with the intent and/or foreseeability that Plaintiffs would rely thereon; and upon which Plaintiffs reasonably relied to their detriment.

362. Defendants knew, or but for their egregious recklessness would have known, that their statements and omissions were false and/or misleading at the time they were made.

363. Plaintiffs actually and justifiably relied on Defendants' misrepresentations and/or omissions to their detriment when Plaintiffs purchased Schering securities.

364. Plaintiffs would not have acquired Schering securities, nor would Plaintiffs have paid the prices that they paid for such securities – which were inflated by Defendants' misconduct – had they known the truth about the matters alleged herein.

365. As a result of Defendants' false and misleading statements and omissions, Plaintiffs suffered monetary injury and punitive damages, the amount of which will be proved at trial herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

A. Awarding compensatory damages in favor of Plaintiffs against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

B. Awarding Plaintiffs pre-judgment and post-judgment interest, as well as reasonable costs and expenses incurred in the action, including counsel fees and expert fees; and

C. Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiffs hereby demand a trial by jury as to all issues so triable.

Dated: November 19, 2013

KIRBY McINERNEY LLP

By: _____

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Plaintiffs' Counsel

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

In accordance with Local Civil Rule 11.2, I, Karina Kosharskyy, attorney for the Plaintiffs in the above-referenced action, hereby certify that to the best of my knowledge and belief, the matter in controversy is also the subject of a pending class action, captioned *In re Schering-Plough Corporation/ENHANCE Securities Litigation*, No. 08-cv-397 (DMC) (JAD) (D.N.J.).

I certify under penalty of perjury that the foregoing is true and correct.

Dated: November 19, 2013

Karina Kosharskyy